EXHIBIT 6

ISSUE CLASSIFICATION	
Class	Subclass
604	232

U.S. UTILITY PATENT APPLICATION

O.I.P.E.	PATENT DATE
SCANNED DWP O.G. DIT	MAY 13 2003

SECTOR	CLASS	SUBCLASS	ART UNIT	EXAMINER
	604		3743	

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PREPARED AND APPROVED FOR ISSUE

ISSUING CLASSIFICATION

ORIGINAL		CROSS REFERENCE(S)	
CLASS	SUBCLASS	CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)
604	232		
INTERNATIONAL CLASSIFICATION			
A61M 5/00			

☐ Continued on Issue Slip Inside File Jacket

☐ TERMINAL DISCLAIMER	DRAWINGS			CLAIMS ALLOWED	
	Sheets Drwg.	Figs. Drwg.	Print Fig.	Total Claims	Print Claim for O.G.
	2	4	1	7	2

☐ a) The term of this patent subsequent to _____ (date) has been disclaimed.	Kevin C. Sirmon (Assistant Examiner) (Date)	NOTICE OF ALLOWANCE MAILED: 9-20-02
☐ b) The term of this patent shall not extend beyond the expiration date of U.S Patent. No. _____.	BRIAN L. CASLER SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700 (Primary Examiner) 9/18/02 (Date)	ISSUE FEE: Amount Due $1280.00; Date Paid 12-18-02
☐ c) The terminal ____months of this patent have been disclaimed.	S Green (Legal Instruments Examiner) 9-25-02 (Date)	ISSUE BATCH NUMBER

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Form PTO-436A (Rev 6/02)

ISSUE FEE IN FILE

DRAWINGS IN FILE

(LABEL AREA)

(FACE)

PATENT APPLICATION

09348536

Jc138 U.S. PTO
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07/07/99

INITIALS MTW

CONTENTS

		Date received (Incl. C. of M.) or Date Mailed			Date received (Incl. C. of M.) or Date Mailed
1.	Application ____ papers.		42.		
2.	Unsigned Dec	8/5/99	43.		
3.	Dec + Surcharge	10-12-99	44.		
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5.	Pre Amdt B	7.7.99	46.		
6.	Info Disclosure Stmt	3/9/00	47.		
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27.	Drawings (2 sht)		68.		
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ISSUE SLIP STAPLE AREA (for additional cross references)

POSITION	INITIALS	ID NO.	DATE
FEE DETERMINATION			7/14/99
O.I.P.E. CLASSIFIER	MTW	51	7/21-99
FORMALITY REVIEW	RF	70556	8-5-99
	RF	70556	10-20-99

INDEX OF CLAIMS

✔ ..... Rejected
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I ..... Interference
A ..... Appeal
O ..... Objected

Claim Final	Claim Original	Date
	1	12/2/98
	2	2/19/99
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SEARCHED

Class	Sub.	Date	Exmr.
604	200-201 228 232-234	11/21/00	KCS
Same	as above	9/17/02	KCS

INTERFERENCE SEARCHED

Class	Sub.	Date	Exmr.
Same as	above	9/17/02	KCS

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(INCLUDING SEARCH STRATEGY)

	Date	Exmr.
M. Backelman	11/21/00	KCS

(RIGHT OUTSIDE)

US006562011B1

(12) **United States Patent**
Buch-Rasmussen et al.

(10) **Patent No.: US 6,562,011 B1**
(45) **Date of Patent: May 13, 2003**

(54) **MEDICATION DELIVERY DEVICE**

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(73) Assignee: **Novo Nordisk A/S**, Bagsvaerd (DK)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/348,536**

(22) Filed: **Jul. 7, 1999**

Related U.S. Application Data

(60) Provisional application No. 60/098,702, filed on Sep. 1, 1998.

(30) **Foreign Application Priority Data**

Jul. 8, 1998 (DK) 1998 00909
Nov. 17, 1998 (DK) 1998 01500

(51) **Int. Cl.**[7] **A61M 5/00**
(52) **U.S. Cl.** **604/232**
(58) **Field of Search** 604/200–201, 604/228, 232–234

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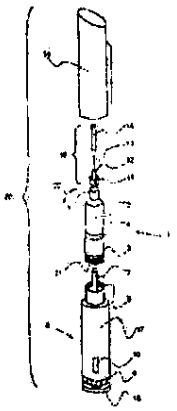
* cited by examiner

Primary Examiner—Brian L. Casler
Assistant Examiner—Kevin C. Simmons
(74) *Attorney, Agent, or Firm*—Marc A. Began, Esq.; Richard W. Bork, Esq.; Reza Green, Esq.

(57) **ABSTRACT**

The present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly. The cartridge assembly comprises a cartridge having a stopper adapted to receive a plunger means. Furthermore, the cartridge assembly has one end sealed with a pierceable sealing, said end comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly. At least one of the coupling means of the cartridge assembly is unitarily moulded with the cartridge. The dosing assembly comprises a plunger means and has coupling means for engaging the cartridge assembly. The cartridge assembly and the dosing assembly are coupled together for delivering selected doses of medication. The cartridge is preferably moulded from a plastic material, such as a transparent material, and may be housed in a cartridge housing for protection of the cartridge. The coupling means may be selected from threaded locks, snap locks, hinged locks, or bajonet locks. The medication delivery device is especially suitable for delivering insulin, growth hormone or other medicines.

7 Claims, 2 Drawing Sheets



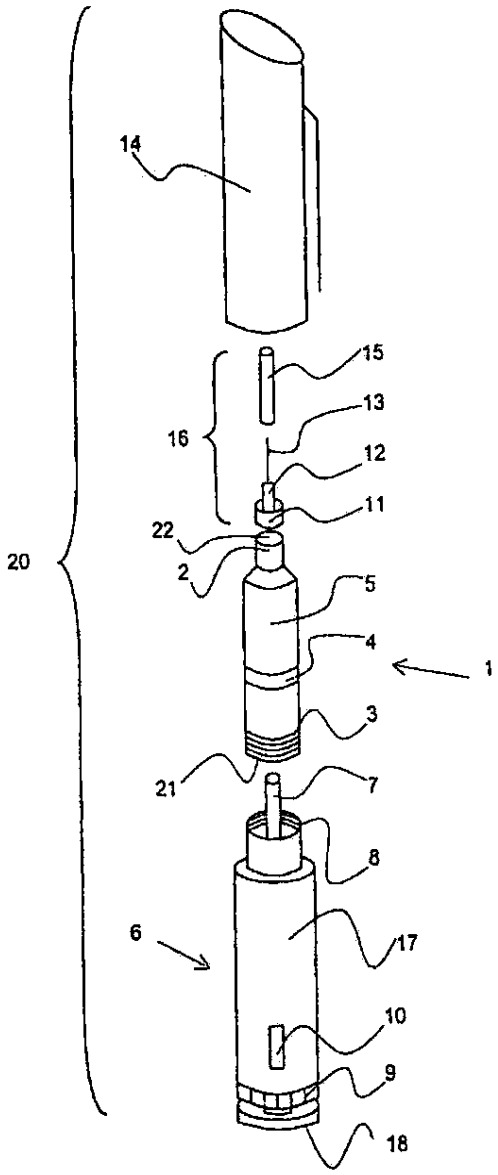


Fig. 1

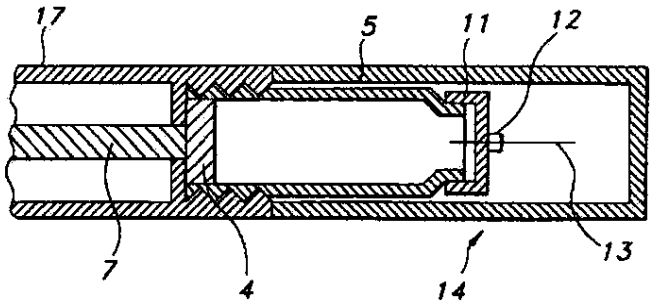


FIG. 2A

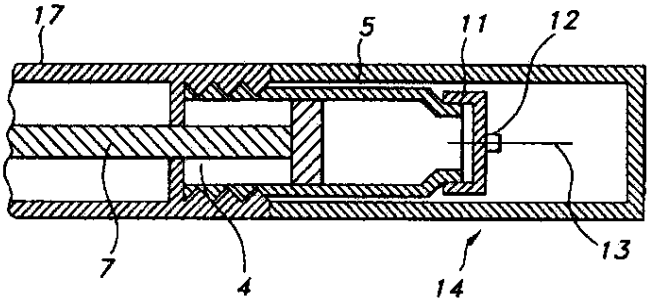


FIG. 2B

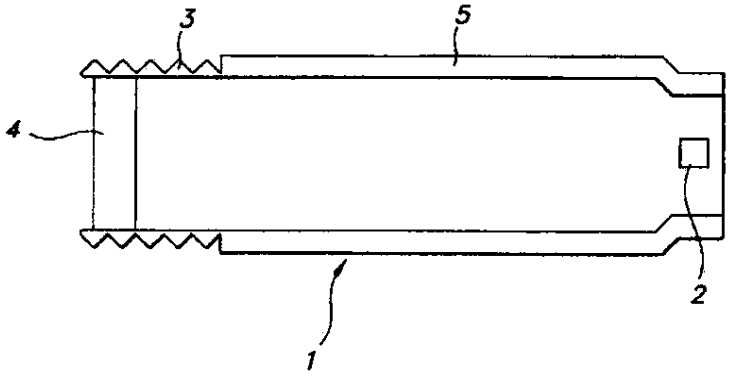


FIG. 3

MEDICATION DELIVERY DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. 119 of Danish application nos. PA 1998 00909 filed Jul. 8, 1998 and PA 1998 01500 filed Nov. 17, 1998, and U.S. provisional application No. 60/098,702 filed Sep. 1, 1998, the contents of which are fully incorporated herein by reference.

The present invention relates to a medication delivery device having a cartridge and a dosing assembly coupled together for delivering selected doses of medication, wherein at least one of the coupling means of the cartridge is unitarily moulded with the cartridge.

BACKGROUND

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the day. The required insulin dose will vary from patient to patient, and will for each patient often also vary during the day. Each patient will often establish a regimen for the insulin administration adjusted to his or her insulin need as well as lifestyle. Medication delivery pens have been developed to facilitate the self-administration of medication, such as insulin.

One prior art medication delivery pen includes a pen body assembly comprising a medication cartridge and a plunger device. A needle assembly may be connected to the pen body assembly. The medication is delivered by moving or pressing a plunger in the direction of the needle assembly thereby delivering the medication. When the medication in the cartridge is exhausted the pen body assembly is discarded. Depending on the medication needs for each individual the medication in the cartridge will last for several days. During this period the needle assembly will often have to be replaced by a new assembly or new needle due to increasing bluntness of the needle making injections painful for the patient.

More recent developments have revealed medication delivery pens, wherein the cartridge holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, discarded and replaced by a new medicine-containing cartridge assembly.

An example of this is shown in EP 0 688 571 disclosing a medication delivery pen having a reusable pen body assembly and a disposable cartridge assembly that are threadedly engageable with one another. The cartridge assembly comprises a cartridge, a cartridge housing, a cap between the distal end of the cartridge and the housing, securing the cartridge in the housing and being adapted for engagement with a needle assembly. Furthermore, the cartridge comprises a plunger within the cartridge. The reusable pen body assembly is coupled through a threaded coupling to the cartridge housing. Thus, the total number of parts comprising the prior art cartridge assembly is high.

It is an object of the present invention to provide a medication delivery device wherein the amount of parts of the cartridge is minimized.

SUMMARY OF THE INVENTION

Accordingly, the present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly,

said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, the cartridge further comprising a stopper adapted to receive plunger means, and

said dosing assembly comprising plunger means has coupling means for engaging the cartridge assembly, and said plunger means is adapted to engage the stopper of the cartridge when the dosing assembly is coupled to the cartridge.

The unitarily moulded coupling or coupling ensure that the coupling is not accidentally released from the cartridge during use and storage. Also, the above-described medication delivery device has fewer parts that the prior art devices because at least one coupling means is moulded unitarily with the cartridge. Thereby the costs involved in the production and assembling of the device are reduced, and the device is more economical, which is an important feature for a disposable device.

The medical delivering device may either be manufactured as a disposable device which is sold pre-filled with the insulin or it may appear as a durable medical delivering device so designed that it can receive disposable cartridges with insulin.

In a preferred embodiment the dosing assembly is reusable and the cartridge assembly is disposable, and accordingly, a second aspect of the present invention is a medication delivery device wherein the dosing assembly is releasably coupled to the cartridge assembly.

The medication delivery device is preferably constructed so as to ensure that the plunger means abuts on the stopper during use of the device, such as attaching and releasing the needle assembly. It is understood that the plunger means must disengage the stopper when the cartridge assembly is deliberately released from a reusable dosing assembly because the medication in the cartridge has been exhausted and the cartridge assembly is to be discarded. In this situation the plunger means is to be retracted to the dosing assembly before assembling the device with a new cartridge assembly.

Securing the abutment of the plunger means on the stopper during use of the medication delivery device, in particular when the needle assembly is coupled to and/or decoupled from the cartridge assembly, may be carried out by a variety of means. In a preferred embodiment the abutment is secured by preventing the cartridge assembly from being inadvertently released from the dosing assembly.

In particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dosing assembly. Thus, in that respect examples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks. Another preferred embodiment includes a safety on the coupling between the dosing assembly and the cartridge assembly, such as hinge on the coupling or a threaded coupling releasable only after exerting an axial pressure on the coupling.

A second aspect of the present invention is a cartridge assembly for use in a medication delivery device, said

cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, said cartridge further comprising a stopper.

The cartridge assembly may further comprise a cartridge housing for protecting the cartridge in use. Furthermore, when the cartridge is moulded unitarily with one coupling means the cartridge housing may comprise the other coupling means. Accordingly, in one embodiment of the invention the housing of the cartridge assembly comprises coupling means for coupling the cartridge assembly to the dosing assembly, preferably the coupling means is moulded unitarily with the housing. The cartridge is arranged within the cartridge housing. The cartridge housing may be non-releasably attached to the cartridge, once the cartridge is arranged in the housing, whereby the housing is disposed with the cartridge. In another embodiment the housing is reusable and the cartridge is arranged releasably in the housing.

In a preferred embodiment all the coupling means of the cartridge assembly are unitarily moulded with the cartridge. Thereby, it is possible to construct the cartridge assembly without the housing providing a cartridge assembly with even fewer parts.

The coupling means of the cartridge assembly may be for any suitable coupling, preferably a releasable coupling. Examples of the coupling are snap locks, such as snap locks with guidewire and sideways snap locks, snap locks released through threads, bajonet locks, luer locks, hinged locks, threaded locks and any suitable combinations thereof.

The coupling means unitarily moulded with the cartridge are preferably external coupling means, such as an external threaded coupling.

In particular the coupling means for engaging to the dosing means may be an external threaded coupling.

The cartridge may be moulded from any material suitable for medical containers. The cartridge is preferably moulded from a plastic material, e.g. by injection moulding. A suitable choice of material allows the cartridge to be at least partly transparent, whereby the user can see whether content, such as liquid is left in the cartridge. In a preferred embodiment the cartridge is totally transparent giving the user a greater possibility of inspecting the content of the cartridge.

By using a plastic material as compared to the usual glass material a great advantage is achieved in the production lines. Normally a significant quantity of the produced glass cartridges will be spoiled in the lines due to breakage, however the loss is greatly reduced by the use of plastic cartridges. Furthermore, the risk of small loose glass particles in the cartridges have been eliminated.

Also, by moulding the coupling(s) unitarily with the cartridge a very precise coupling mechanism may be obtained, since no further steps are to be taken to attach coupling means to the cartridge.

The cartridge may be of any suitable form, such as a cylinder. The cylinder may be constructed with various combinations of circular or non-circular inner and outer cross-section. In another embodiment the cartridge may be box-shaped having essentially rectangular or triangular cross-section.

The stopper is in sliding fluid tight engagement in the cartridge. The stopper is preferably made of plastic and/or rubber material.

The flexibility of the cartridge wall is not critical, however if the cartridge is too flexible the function of the stopper may be impaired. Mostly, the cartridge is made of a material only slightly flexible to non-flexible.

In order to enforce and strengthen the cartridge wall the cartridge may be integrally moulded with reinforcements. Thereby, the necessity of a protective housing may be obviated. Furthermore, a scale may be integrally moulded with the cartridge wall providing the user with a measure for the medication used and left.

In a most preferred embodiment the cartridge assembly is comprised only of a cartridge being sealed in one end with a sealing, being unitarily moulded with all couplings means and comprising a stopper.

In a cylindrical cartridge the two couplings of the cartridge assembly are generally opposing each other having the same axis. However, the coupling for engaging with the dosing assembly being separate from coupling for engaging the needle assembly may be arranged so that their axis are in any angle with respect to each other, such as perpendicular, or even parallel, but not overlapping.

Another aspect of the present invention is a cartridge being at least partly filled with liquid medication, such as insulin.

In another embodiment the invention relates to a medication delivery device for transferring medication from the cartridge into a syringe with a needle. In this embodiment the coupling means for engaging the needle assembly may be replaced by coupling means for engaging the syringe, or coupling means for both may be provided. The coupling means may be a syringe holder, for example a cylinder coupled to the cartridge comprising a central bore for receiving the syringe. The syringe is coupled to the cartridge having the needle piercing the sealing. By activation of the dosing means the metered amount of medication is driven into the syringe. The syringe is then ready for injection after being removed from the cartridge.

DRAWINGS

FIG. 1 is an exploded perspective view of the medication delivery device.

FIG. 2 is a cross-sectional view showing part of the medication delivery device, *2a* immediately after assembling before the first injection, and *2b* after some time of use.

FIG. 3 is a cross-sectional view showing the cartridge before assembling of the medication delivery device.

DETAILED DESCRIPTION OF THE INVENTION

A medication delivery device in accordance with the present invention is identified generally by the numeral **20** in FIGS. 1 and 2. Medication delivery device **20** includes a dosing assembly **6**, and cartridge assembly **1**, a needle assembly **16** and a cap **14**.

The dosing assembly **6** is illustrated in FIGS. 1 and 2. It is understood, however, that the dosing assembly **6** according to the invention may be any suitable dosing unit including plunger means, and accordingly, that variations from the depicted embodiment may be provided, and are considered to be within the scope of this invention. In the depicted embodiment the dosing assembly **6** includes a cylindrical housing surrounding the plunger means **17** of the dosing unit and having opposed proximal and distal ends.

In one aspect of the invention the plunger means comprises a rod element **7** which is adapted to engage the stopper **4** of the cartridge assembly **1**. The rod element **7** advances

axially into the cartridge 5 during injections. The dosing assembly may have any suitable driving means for advancing the rod element 7.

The dosing unit 6 preferably also comprises scale means 10 indicating the dosing quantity selected by activating the dose setting means 9 for defining specified selected doses of medication to be delivered. The selected dose may be delivered by actuating the actuator button 18. The actuator button is part of the driving means of the dosing assembly exerting its force on the rod element 7.

The dosing assembly further comprises coupling means 8 adapted for engagement with the cartridge assembly. The coupling means 8 may be internal or external couplings. In a preferred embodiment the coupling 8 is an internal coupling.

The cartridge assembly 1 is illustrated in FIGS. 1 and 2, and in greater detail in FIG. 3. In FIG. 1 cartridge assembly 1 includes a moulded cartridge 5 extending from proximal end 21 to distal end 22.

At the distal end 22 of the cartridge assembly 1 is provided coupling means 2 for releasably mounting a needle assembly 11. At the proximal end 21 of the cartridge assembly 1 is provided coupling means 3 for mounting a dosing assembly 6. The coupling means are as described above.

Cartridge 5 also comprises a stopper 4 in sliding fluid tight engagement within said cartridge 5. The stopper 4 is adapted to receive the plunger means, such as a rod element 7 of the dosing assembly 6. The rod element 7 is adapted to exert an axial movement of the stopper 4 towards the sealed end 22 of the cartridge 5.

The cartridge assembly 1 may further comprise a housing for protecting some or all of the cartridge 5. When the cartridge assembly 1 includes a housing, one of the couplings 2, 3 of the cartridge may be moulded unitarily with the housing.

Instead of the protective housing the cartridge 5 may have integrally moulded reinforcements of the cartridge wall.

The depicted cartridge 5 is cylindrical having couplings 2, 3 at opposed ends. However, the cartridge may obtain any suitable form and the cross-section may be circular or non-circular, such as substantially triangular or oval.

The device according to the invention may include a protective cap 14 that is removably mounted over the cartridge assembly 1 and/or the needle 11 and which is removed before injection of the medication in the cartridge 5. The cap further ensures that the content of the cartridge is protected against sunlight.

Referring to FIG. 3 the coupling means of the cartridge are shown in greater detail. The coupling means 3 is an external thread, whereas the coupling means 2 is a recess for a snap lock of the needle assembly. Both coupling means are moulded unitarily with the cartridge.

The various parts of the medication delivery device are advantageously made of plastics, e.g. by injection moulding.

The medication delivery device 20 may further comprise any appropriate needle assembly 11, such as a double ended needle 13 having opposed proximal and distal points and a lumen extending axially therebetween.

A mounting hub 12 is engaged on the needle 13 and is removably connected to the coupling means 2 at the needle end of the cartridge assembly. The relative location of the mounting hub 12 ensures that the proximal point of the needle 13 will pierce the sealing when the mounting hub 12 is engaged with the coupling means 2 on the cartridge assembly 1.

The needle assembly 11 may further comprise a removable shield or cap 15 for protecting against accidental needle sticks.

The device according to the invention is suitable for delivering pre-set dosages of insulin, it is however understood that the device is suitable for the injection of pre-set dosages of other liquids.

In use the user will set the dose by means of the dose setting means 9. Before activating the actuator button 18 the cap 14 must be removed from the cartridge assembly 1 whereby the device 20 is prepared for an injection. The injection is effected by activating the actuator button 18, which again will cause the stopper 4 to be moved towards the sealed end 22 of the cartridge 5, thereby delivering the desired pre-set dosage. A subsequent dosage of medication will be set in exactly the same manner as described above. However, for such a subsequent dosage, the rod element 7 and the stopper 4 will be in a partly advanced position as starting point. Dose setting and injections can be carried out until all of the medication has been used.

What is claimed is:

1. A medication delivery device comprising a cartridge assembly having opposite ends and a dosing assembly for setting a desired dose and acting on the cartridge assembly to cause the desired dose to be delivered, wherein:

the cartridge assembly includes a molded cartridge and a stopper disposed in the cartridge, wherein one end of the cartridge assembly is sealed with a pierceable sealing, wherein the one end includes a first coupling means for releasably mounting a needle assembly having a skin-piercing needle, and wherein the other end of the cartridge assembly includes a second coupling means for engaging the dosing assembly, wherein at least one of the coupling means is unitarily molded with the cartridge, and wherein the dosing assembly includes a housing, a plunger, and a mechanism for setting a desired dose and for moving the plunger relative to the housing in an axial direction for administering a set dose, and wherein the dosing assembly housing includes a coupling member for engaging the second coupling means of the cartridge assembly for securing the housing against axial movement relative to the cartridge assembly such that the plunger engages the stopper for moving the stopper in response to the plunger movement wherein the at least one coupling means of the cartridge assembly is a threaded coupling and wherein the second coupling means is an external threaded coupling.

2. The medication delivery device according to claim 1, wherein both said coupling means of said cartridge assembly are unitarily molded with the cartridge.

3. The medication delivery device according to claim 1, wherein the said at least one coupling means of said cartridge assembly is an external coupling.

4. The medication delivery device according to claim 1, wherein the cartridge is molded of a plastic material.

5. The medication delivery device according to claim 4, wherein the cartridge is at least partly transparent.

6. The medication delivery device according to claim 1, wherein the dosing assembly further comprises a scale.

7. The medication delivery device according to claim 1, wherein the coupling means of the cartridge assembly are opposed.

* * * * *

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

7/20/1999 MPEOPLES 00000053 141447 09348536
FC:101 760.00 CH
FC:103 90.00 CH

PTO-1556
(5/87)

*U.S. GPO: 1998-433-214/80404

Abstract

The present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly. The cartridge assembly comprises a cartridge having a stopper adapted to receive a plunger means. Furthermore, the cartridge assembly has one end sealed with a pierceable sealing, said end comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly. At least one of the coupling means of the cartridge assembly is unitarily moulded with the cartridge. The dosing assembly comprises a plunger means and has coupling means for engaging the cartridge assembly. The cartridge assembly and the dosing assembly are coupled together for delivering selected doses of medication. The cartridge is preferably moulded from a plastic material, such as a transparent material, and may be housed in a cartridge housing for protection of the cartridge. The coupling means may be selected from threaded locks, snap locks, hinged locks, or bajonet locks. The medication delivery device is especially suitable for delivering insulin, growth hormone or ~~the like~~ other medicines.

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The present invention relates to a medication delivery device having a cartridge and a dosing assembly coupled together for delivering selected doses of medication, wherein at least one of the coupling means of the cartridge is unitarily moulded with the cartridge.

Background

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the day. The required insulin dose will vary from patient to patient, and will for each patient often also vary during the day. Each patient will often establish a regimen for the insulin administration adjusted to his or her insulin need as well as lifestyle. Medication delivery pens have been developed to facilitate the self-administration of medication, such as insulin.

One prior art medication delivery pen includes a pen body assembly comprising a medication cartridge and a plunger device. A needle assembly may be connected to the pen body assembly. The medication is delivered by moving or pressing a plunger in the direction of the needle assembly thereby delivering the medication. When the medication in the cartridge is exhausted the pen body assembly is discarded. Depending on the medication needs for each individual the medication in the cartridge will last for several days. During this period the needle assembly will often have to be displaced by a new assembly or new needle due to increasing bluntness of the needle making injections painful for the patient.

More recent developments have revealed medication delivery pens, wherein the cartridge holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, discarded and replaced by a new medicine-containing cartridge assembly.

An example of this is shown in EP 0 688 571 disclosing a medication delivery pen having a reusable pen body assembly and a disposable cartridge assembly that are threadedly engageable with one another. The cartridge assembly comprises a cartridge, a cartridge housing, a cap between the distal end of the cartridge and the housing, securing the cartridge in the housing and being adapted for engagement

with a needle assembly. Furthermore, the cartridge comprises a plunger within the cartridge. The reusable pen body assembly is coupled through a threaded coupling to the cartridge housing. Thus, the total number of parts comprising the prior art cartridge assembly is high.

It is an object of the present invention to provide a medication delivery device wherein the amount of parts of the cartridge is minimised.

Summary of the invention

Accordingly, the present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly,

said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, the cartridge further comprising a stopper adapted to receive plunger means, and

said dosing assembly comprising plunger means has coupling means for engaging the cartridge assembly, and said plunger means is adapted to engage the stopper of the cartridge when the dosing assembly is coupled to the cartridge.

The unitarily moulded coupling(s) or couplings ensure that the coupling is not accidentally released from the cartridge during use and storage. Also, the above-described medication delivery device has fewer parts that the prior art devices because at least one coupling means is moulded unitarily with the cartridge. Thereby the costs involved in the production and assembling of the device are reduced, and the device is more economical, which is an important feature for a disposable device.

The medical delivering device may either be manufactured as a disposable device which is sold pre-filled with the insulin or it may appear as a durable medical delivering device so designed that it can receive disposable cartridges with insulin.

In a preferred embodiment the dosing assembly is reusable and the cartridge assembly is disposable, and accordingly, a second aspect of the present invention is a medication delivery device wherein the dosing assembly is releasably coupled to the cartridge assembly.

The medication delivery device is preferably constructed so as to ensure ~~secure~~ that the plunger means abuts on the stopper during use of the device, such as attaching and releasing the needle assembly. It is understood that the plunger means must disengage the stopper when the cartridge assembly is deliberately released from a reusable dosing assembly because the medication in the cartridge has been exhausted and the cartridge assembly is to be discarded. In this situation the plunger means is to be retracted to the dosing assembly before assembling the device with a new cartridge assembly.

Securing the abutment of the plunger means on the stopper during use of the medication delivery device, in particular when the needle assembly is coupled to and/or decoupled from the cartridge assembly, may be carried out by a variety of means. In a preferred embodiment the abutment is secured by preventing the cartridge assembly from being inadvertently released from the dosing assembly.

In particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dosing assembly. Thus, in that respect examples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks. Another preferred embodiment includes a safety on the coupling between the dosing assembly and the cartridge assembly, such as hinge on the

coupling or a threaded coupling releasable only after exerting an axial pressure on the coupling.

A second aspect of the present invention is a cartridge assembly for use in a medication delivery device, said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, said cartridge further comprising a stopper.

The cartridge assembly may further comprise a cartridge housing for protecting the cartridge in use. Furthermore, when the cartridge is moulded unitarily with one coupling means the cartridge housing may comprise the other coupling means. Accordingly, in one embodiment of the invention the housing of the cartridge assembly comprises coupling means for coupling the cartridge assembly to the dosing assembly, preferably the coupling means is moulded unitarily with the housing. The cartridge is arranged within the cartridge housing. The cartridge housing may be non-releasably attached to the cartridge, once the cartridge is arranged in the housing, whereby the housing is disposed with the cartridge. In another embodiment the housing is reusable and the cartridge is arranged releasably in the housing.

In a preferred embodiment all the coupling means of the cartridge assembly are unitarily moulded with the cartridge. Thereby, it is possible to construct the cartridge assembly without the housing providing a cartridge assembly with even fewer parts.

The coupling means of the cartridge assembly may be for any suitable coupling, preferably a releasable coupling. Examples of the coupling are snap locks, such as snap locks with guidewire and sideways snap locks, snap locks released through threads, bajonet locks, luer locks, hinged locks, threaded locks and any suitable combinations thereof.

The coupling means unitarily moulded with the cartridge are preferably external coupling means, such as an external threaded coupling.

In particular the coupling means for engaging to the dosing means may be an external threaded coupling.

The cartridge may be moulded from any material suitable for medical containers. The cartridge is preferably moulded from a plastic material, e.g. by injection moulding. A suitable choice of material allows the cartridge to be at least partly transparent, whereby the user can see whether content, such as liquid is left in the cartridge. In a preferred embodiment the cartridge is totally transparent giving the user a greater possibility of inspecting the content of the cartridge.

By using a plastic material as compared to the usual glass material a great advantage is achieved in the production lines. Normally a significant quantity of the produced glass cartridges will be spoiled in the lines due to breakage, however the loss is greatly reduced by the use of plastic cartridges. Furthermore, the risk of small loose glass particles in the cartridges have been eliminated.

Also, by moulding the coupling(s) unitarily with the cartridge a very precise coupling mechanism may be obtained, since no further steps are to be taken to attach coupling means to the cartridge.

The cartridge may be of any suitable form, such as a cylinder. The cylinder may be constructed with various combinations of circular or non-circular inner and outer cross-section. In another embodiment the cartridge may be box-shaped having essentially rectangular or triangular cross-section.

The stopper is in sliding fluid tight engagement in the cartridge. The stopper is preferably made of plastic and/or rubber material.

The flexibility of the cartridge wall is not critical, however if the cartridge is too flexible the function of the stopper may be impaired. Mostly, the cartridge is made of a material only slightly flexible to non-flexible.

In order to enforce and strengthen the cartridge wall the cartridge may be integrally moulded with reinforcements. Thereby, the necessity of a protective housing may be

Detailed description of the invention

A medication delivery device in accordance with the present invention is identified generally by the numeral 20 in Fig. 1 and 2. Medication delivery device 20 includes a dosing assembly 6, and cartridge assembly 1, a needle assembly 16 and a cap 14.

The dosing assembly 6 is illustrated in Fig. 1 and 2. It is understood, however, that the dosing assembly 6 according to the invention may be any suitable dosing unit including plunger means, and accordingly, that variations from the depicted embodiment may be provided, and are considered to be within the scope of this invention. In the depicted embodiment the dosing assembly 6 includes a cylindrical housing surrounding the plunger means 17 of the dosing unit and having opposed proximal and distal ends.

In one aspect of the invention the plunger means comprises a rod element 7 which is adapted to engage the stopper 4 of the cartridge assembly 1. The rod element 7 advances axially into the cartridge 5 during injections. The dosing assembly may have any suitable driving means for advancing the rod element 7.

The dosing unit 6 preferably also comprises scale means 10 indicating the dosing quantity selected by activating the dose setting means 9 for defining specified selected doses of medication to be delivered. The selected dose may be delivered by actuating the actuator button 18. The actuator button is part of the driving means of the dosing assembly exerting its force on the rod element 7.

The dosing assembly further comprises coupling means 8 adapted for engagement with the cartridge assembly. The coupling means 8 may be internal or external couplings. In a preferred embodiment the coupling 8 is an internal coupling.

The cartridge assembly 1 is illustrated in Fig. 1 and 2, and in greater detail in Fig. 3. In Fig. 1 cartridge assembly 1 includes a moulded cartridge 5 extending from proximal end 21 to distal end 22.

At the distal end 22 of the cartridge assembly 1 is provided coupling means 2 for releasably mounting a needle assembly 11. At the proximal end 21 of the cartridge assembly 1 is provided coupling means 3 for mounting a dosing assembly 6. The coupling means are as described above.

Cartridge 5 also comprises a stopper 4 in sliding fluid tight engagement within said cartridge 5. The stopper 4 is adapted to receive the plunger means, such as a rod element 7 of the dosing assembly 6. The rod element 7 is adapted to exert an axial movement of the stopper 4 towards the sealed end 22 of the cartridge 5.

The cartridge assembly 1 may further comprise a housing for protecting some or all of the cartridge 5. When the cartridge assembly 1 includes a housing, one of the couplings 2, 3 of the cartridge may be moulded unitarily with the housing.

Instead of the protective housing the cartridge 5 may have integrally moulded reinforcements of the cartridge wall.

The depicted cartridge 5 is cylindrical having couplings 2, 3 at opposed ends. However, the cartridge may obtain any suitable form and the cross-section may be circular or non-circular, such as substantially triangular or oval.

The device according to the invention may include a protective cap 14 that is removably mounted over the cartridge assembly 1 and/or the needle 11 and which is removed before injection of the medication in the cartridge 5. The cap further ensures that the content of the cartridge is protected against sunlight.

Referring to Fig. 3 the coupling means of the cartridge are shown in greater detail. The coupling means 3 is an external thread, whereas the coupling means 2 is a recess for a snap lock of the needle assembly. Both coupling means are moulded unitarily with the cartridge.

The various parts of the medication delivery device are advantageously made of plastics, e.g. by injection moulding.

The medication delivery device 20 may further comprise any appropriate needle assembly 11, such as a double ended needle 13 having opposed proximal and distal points and a lumen extending axially therebetween.

A mounting hub 12 is engaged on the needle 13 and is removably connected to the coupling means 2 at the needle end of the cartridge assembly. The relative location of the mounting hub 12 ensures that the proximal point of the needle 13 will pierce the sealing when the mounting hub 12 is engaged with the coupling means 2 on the cartridge assembly 1.

The needle assembly 11 may further comprise a removable shield or cap 15 for protecting against accidental needle sticks.

The device according to the invention is suitable for delivering pre-set dosages of insulin, it is however understood that the device is suitable for the injection of pre-set dosages of other liquids.

In use the user will set the dose by means of the dose setting means 9. Before activating the actuator button 18 the cap 14 must be removed from the cartridge assembly 1 whereby the device 20 is prepared for an injection. The injection is effected by activating the actuator button 18, which again will ~~effect~~ cause the stopper 4 to be moved towards the sealed end 22 of the cartridge 5, thereby delivering the desired pre-set dosage. A subsequent dosage of medication will be set in exactly the same manner as described above. However, for such a subsequent dosage, the rod element 7 and the stopper 4 will be in a partly advanced position as starting point. Dose setting and injections can be carried out until all of the medication has been used.

Claims:

1. A medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly,

said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, the cartridge further comprising a stopper adapted to receive plunger means, and

said dosing assembly comprising plunger means having coupling means for engaging the cartridge, and said plunger means is adapted to engage the stopper of the cartridge when the dosing assembly is coupled to the cartridge.

2. The medication delivery device according to claim 1, wherein all the coupling means of the cartridge assembly are unitarily moulded with the cartridge.

3. The medication delivery device according to claim 1, wherein at least one coupling means of the cartridge is an external coupling.

4. The medication delivery device according to claim 1, wherein at least one coupling means of the cartridge is a threaded coupling.

5. The medication delivery device according to claim 4, wherein the coupling means for engaging to dosing means is an external threaded coupling.

6. The medication delivery device according to claim 1, wherein the cartridge is moulded of a plastic material.

7. The medication delivery device according to claim 6, wherein the cartridge is at least partly transparent.

8. The medication delivery device according to claim 1, wherein reinforcements of the cartridge wall are integrally moulded with the cartridge.

9. The medication delivery device according to claim 1, wherein the cartridge further comprises a cartridge housing.

10. The medication delivery device according to claim 1, wherein the cartridge further comprise a scale.

11. The medication delivery device according to claim 1, wherein the cross-section of the cartridge is non-circular.

12. The medication delivery device according to claim 1, wherein the coupling means of the cartridge are opposed each other.

13. The cartridge assembly for use in a medication delivery device, said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, said cartridge further comprising a stopper.

14. The cartridge assembly according to claim 13, wherein all the coupling means of the cartridge are unitarily moulded with the cartridge.

15. The cartridge assembly according to claim 13, wherein at least one coupling means of the cartridge is an external coupling.

16. The cartridge assembly according to claim 13, wherein at least one coupling means of the cartridge is a threaded coupling.

17. The cartridge assembly according to claim 16, wherein the coupling means for engaging to dosing means is an external threaded coupling.

18. A cartridge assembly according to claim 13, wherein the cartridge is moulded of a plastic material.

19. A cartridge assembly according to claim 13, wherein the cartridge is at least partly transparent.

20. A cartridge assembly according to claim 13, wherein reinforcements of the cartridge wall are integrally moulded with the cartridge.

21. A cartridge assembly according to claim 13, wherein the cartridge further comprises a cartridge housing.

22. A cartridge assembly according to claim 13, wherein the cartridge further comprise a scale.

23. A cartridge assembly according to claim 13, wherein the cross-section of the cartridge is non-circular.

24. A cartridge assembly according to claim 13, wherein the coupling means of the cartridge are opposed each other.

25. A cartridge assembly according to claim 13, which is filled with medicine.

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY
(Includes Reference to PCT International Applications)

Attorney Docket Number: 5 .200-US

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Medication Delivery Device

the specification of which (check only one item below):

[ ] is attached hereto

[X] was filed as United States application

Application No. to be assigned

on July 7, 1999,

and was amended

on _____

[ ] was filed as PCT international application

Number _____

on _____,

and was amended under PCT Article 19

on _____

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim priority benefits under Title 35, United States Code, §119 of any provisional or foreign applications(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign applications(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR U.S. PROVISONAL/FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (if PCT, indicate "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
Denmark	PA 1998 00909	July 8, 1998	[X] YES [ ] NO
Denmark	PA 1998 01500	November 17, 1998	[X] YES [ ] NO
USA	60/098,702	September 1, 1998	[X] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY
(Includes Reference to PCT International Applications)

Attorney's Docket Number: 200-US

I hereby claim the benefit under Title 35, United States Code §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S. APPLICATIONS		STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	Patented	Pending	Abandoned

PCT APPLICATIONS DESIGNATING THE U.S.					
APPLICATION NO.	FILING DATE	US SERIAL NUMBERS ASSIGNED (if any)			

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

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COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY (Includes Reference to PCT International Applications)					Attorney Docket Number: 5. .200-US
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7	Full Name of Inventor	Family Name:	First Given Name:	Second Given Name:	
	Residence & Citizenship	City:	State or Foreign Country:	Country of Citizenship:	
	Post Office Address	Post Office Address:	City:	State & Zip Code/Country:	
8	Full Name of Inventor	Family Name:	First Given Name:	Second Given Name:	
	Residence & Citizenship	City:	State or Foreign Country:	Country of Citizenship:	
	Post Office Address	Post Office Address:	City:	State & Zip Code/Country:	
9	Full Name of Inventor	Family Name:	First Given Name:	Second Given Name:	
	Residence & Citizenship	City:	State or Foreign Country:	Country of Citizenship:	
	Post Office Address	Post Office Address:	City:	State & Zip Code/Country:	

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature of Inventor 4	Signature of Inventor 5	Signature of Inventor 6
Date	Date	Date
Signature of Inventor 7	Signature of Inventor 8	Signature of Inventor 9
Date	Date	Date
Signature of Inventor 10	Signature of Inventor 11	Signature of Inventor 12
Date	Date	Date

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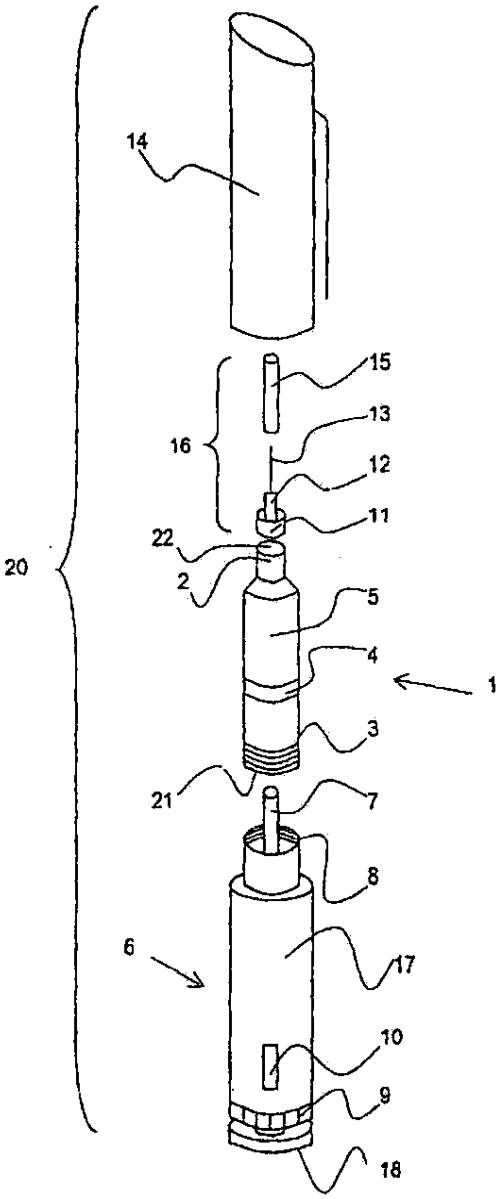

Fig. 1

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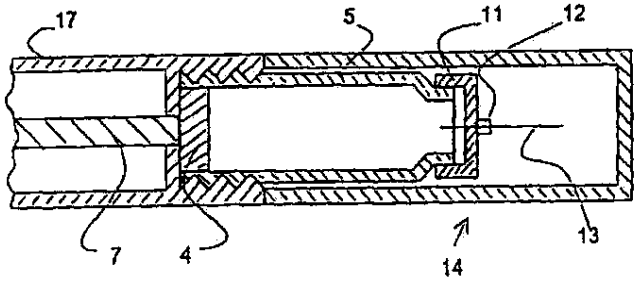

Fig. 2 a

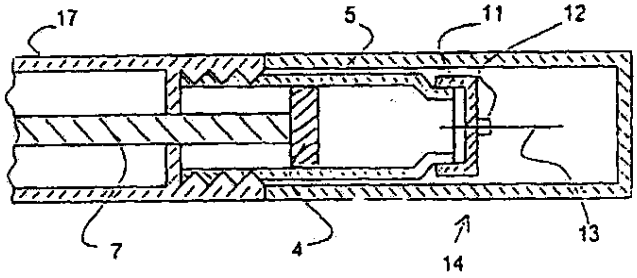

Fig. 2 b

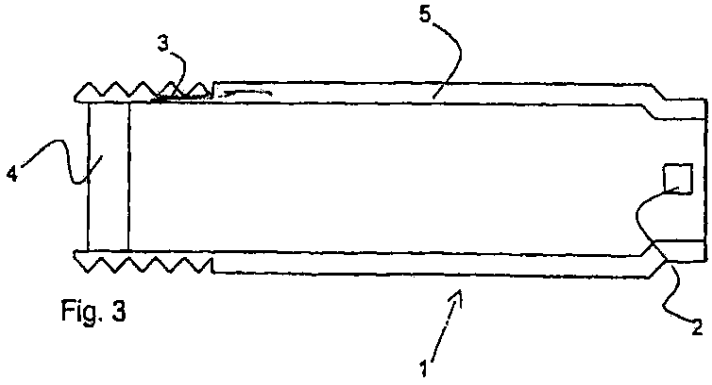

Fig. 3

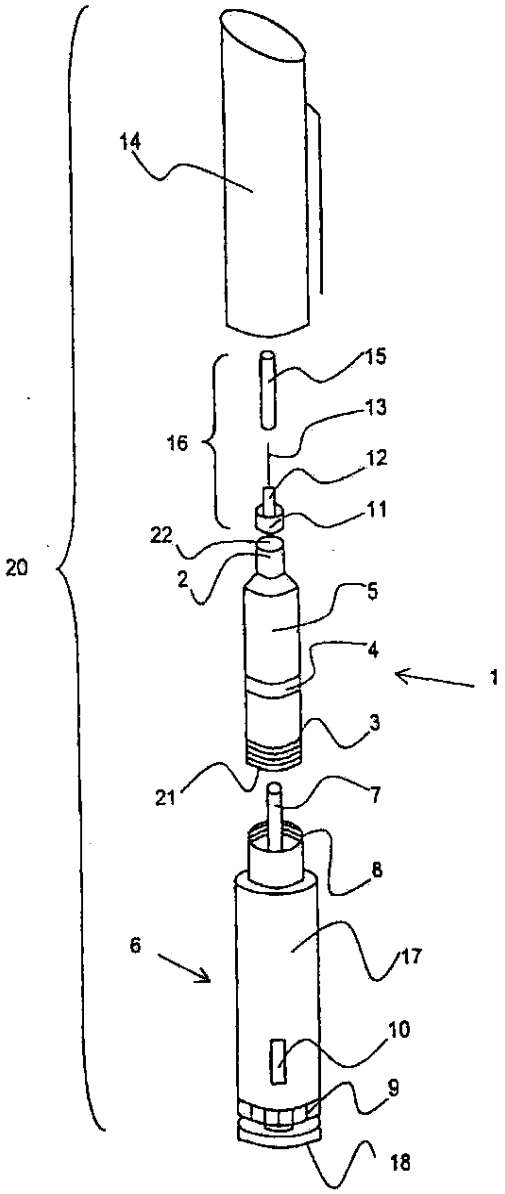

Fig. 1

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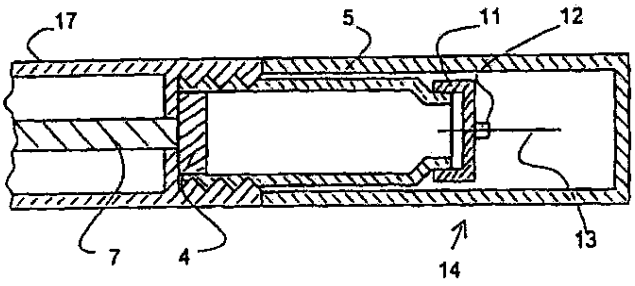

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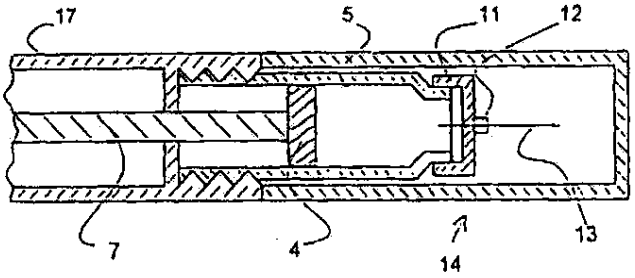

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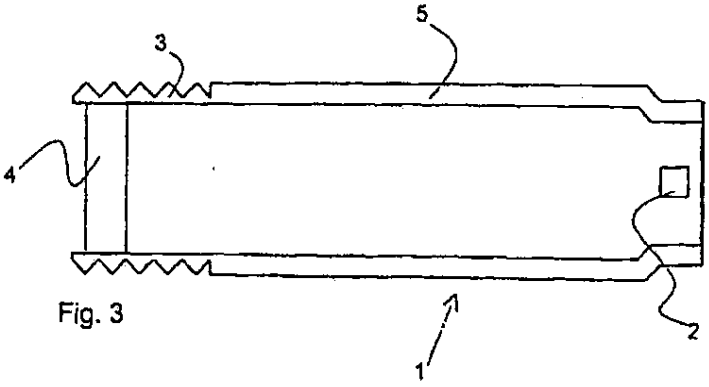


Fig. 3

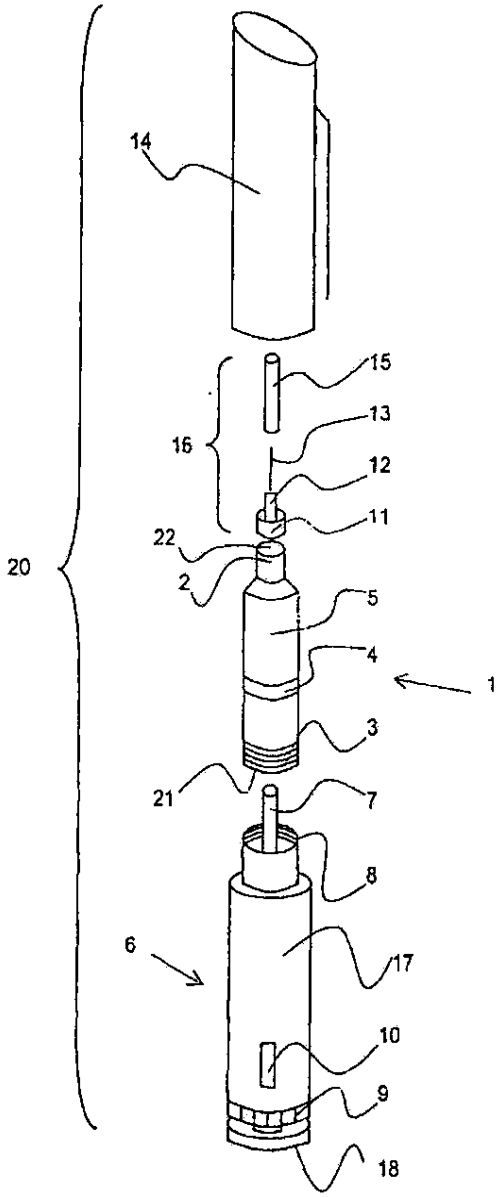


Fig. 1

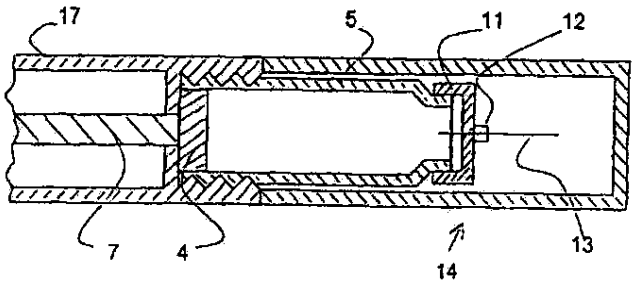


Fig. 2 a

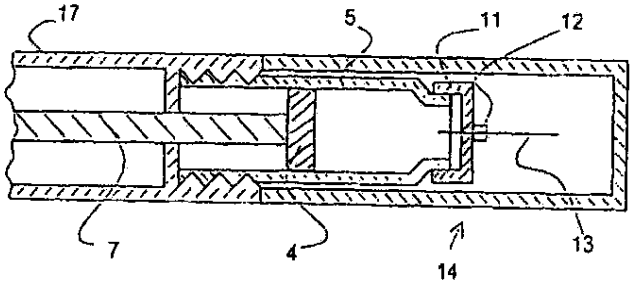


Fig. 2 b

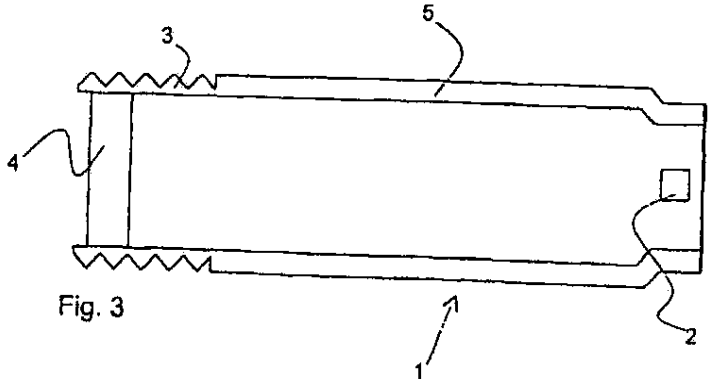


Fig. 3

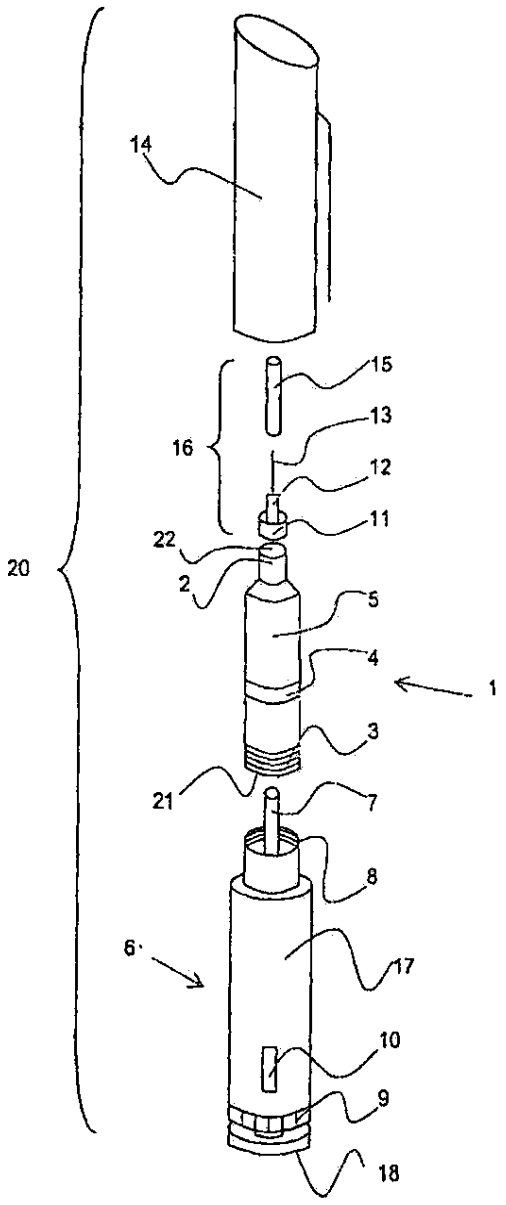


Fig. 1

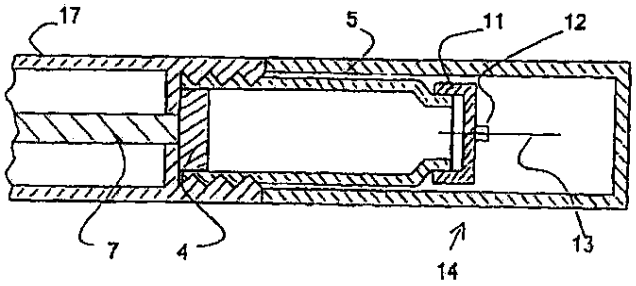


Fig. 2 a

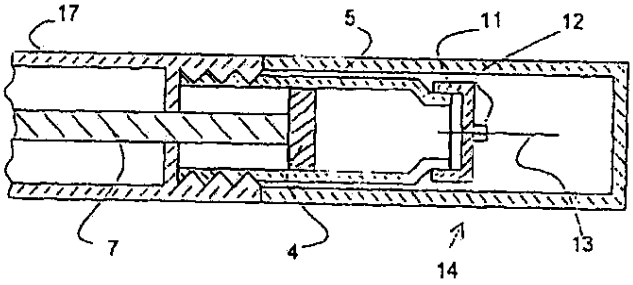


Fig. 2 b

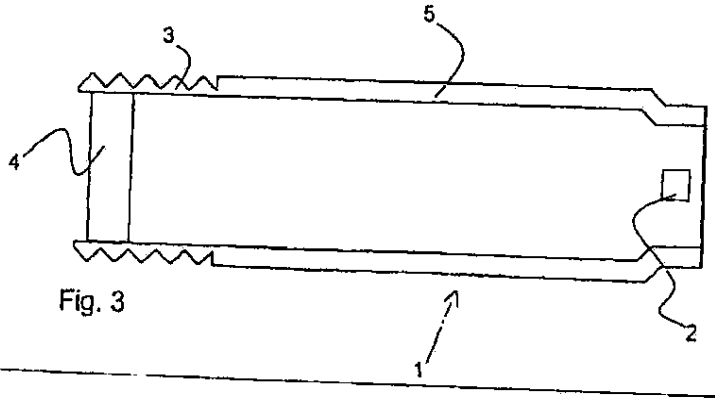


Fig. 3

1 13

PATENT APPLICATION FEE DETERMINATION RECORD
Effective November 10, 1998

Application or Docket Number

CLAIMS AS FILED - PART I

	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA
FOR		
BASIC FEE		
TOTAL CLAIMS	25 minus 20=	* 5
INDEPENDENT CLAIMS	2 minus 3 =	*
MULTIPLE DEPENDENT CLAIM PRESENT		

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY TYPE ☐			OR	OTHER THAN SMALL ENTITY	
RATE	FEE			RATE	FEE
	380.00		OR		760.00
X$ 9=			OR	X$18=	90
X39=			OR	X78=	
+130=			OR	+260=	
TOTAL			OR	TOTAL	850

CLAIMS AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

SMALL ENTITY			OR	OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE			RATE	ADDITIONAL FEE
X$ 9=			OR	X$18=	
X39=			OR	X78=	
+130=			OR	+260=	
TOTAL ADDIT. FEE			OR	TOTAL ADDIT. FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

RATE	ADDITIONAL FEE		OR	RATE	ADDITIONAL FEE
X$ 9=			OR	X$18=	
X39=			OR	X78=	
+130=			OR	+260=	
TOTAL ADDIT. FEE			OR	TOTAL ADDIT. FEE	

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

RATE	ADDITIONAL FEE		OR	RATE	ADDITIONAL FEE
X$ 9=			OR	X$18=	
X39=			OR	X78=	
+130=			OR	+260=	
TOTAL ADDIT. FEE			OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

FORM PTO-875
(Rev 8/98)

Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

SAN00828247

SERIAL NUMBER	FILING DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
09/348,536	07/07/99	604	3734	5637.200-US

APPLICANT

THOMAS BUCH-RASMUSSEN, GENTOFTE, DENMARK; BENNY MUNK, HVIDORRE, DENMARK; JENS ULRIK POULSEN, VIRUM, DENMARK; HENRIK LJUNGREEN, BALLERUP, DENMARK; PETER MOLLER JENSEN, HORSHOLM, DENMARK; JENS MOLLER JENSEN, COPENHAGEN K, DENMARK.

CONTINUING DOMESTIC DATA********
VERIFIED KCS PROVISIONAL APPLICATION NO. 60/098,702 09/01/98
Yes

371 (NAT'L STAGE) DATA********
VERIFIED KCS
None

FOREIGN APPLICATIONS********

VERIFIED KCS			
Yes	DENMARK	PA 1998 00909	07/08/98
	DENMARK	PA 1998 01500	11/17/98

IF REQUIRED, FOREIGN FILING LICENSE GRANTED 08/03/99

Foreign Priority claimed 35 USC 119 (a-d) conditions met ☒yes ☐no ☒yes ☐no ☐Met after Allowance KCS Verified and Acknowledged Examiner's Initials Initials	STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
	DKX	2	25	2

#26

ADDRESS

~~SUSAN T. ELSON, ESQ~~
NOVO NORDISK ~~OF NORTH AMERICA INC~~
~~44 LEXINGTON AVENUE SUITE 6400~~
~~NEW YORK NY 10174-6401~~

MARC A. BEGAN, Esq.
100 College Road West
Princeton, NJ. 08540

TITLE

MEDICATION DELIVERY DEVICE

FILING FEE RECEIVED	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT NO. _____ for the following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit
$980		

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO./TITLE
09/[illegible]	07/07/99	BUCH-RASMUSSEN	[illegible]

0242/0805

STEVE T NELSON ESQ
NOVO NORDISK OF NORTH AMERICA INC
405 LEXINGTON AVENUE SUITE 6400
NEW YORK NY 10174-6401

[illegible] ASSIGNED

[illegible]734

DATE MAILED: 08/05/99

NOTICE TO FILE MISSING PARTS OF APPLICATION
Filing Date Granted

An Application Number and Filing Date have been assigned to this application. The items indicated below, however, are missing. Applicant is given TWO MONTHS FROM THE DATE OF THIS NOTICE within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). **If any of items 1 or 3 through 5 are indicated as missing, the SURCHARGE set forth in 37 CFR 1.16(e) of ☐ $65.00 for a small entity in compliance with 37 CFR 1.27, or ☐ $130.00 for a non-small entity, must also be timely submitted in reply to this NOTICE to avoid abandonment.**

If all required items on this form are filed within the period set above, the total amount owed by applicant as a ☐ small entity (statement filed) ☐ non-small entity is $ 130.00.

☐ 1. The statutory basic filing fee is:
- ☐ missing.
- ☐ insufficient.

Applicant must submit $_____ to complete the basic filing fee and/or file a small entity statement claiming such status (37 CFR 1.27).

☐ 2. The following additional claims fees are due:

$_____for_____total claims over 20.

$_____for_____independent claims over 3.

$_____for multiple dependent claim surcharge.

Applicant must either submit the additional claim fees or cancel additional claims for which fees are due.

☑ 3. The oath or declaration:
- ☑ is missing or unsigned.
- ☐ does not cover the newly submitted items.

An oath or declaration in compliance with 37 CFR 1. 63, including residence information and identifying the application by the above Application Number and Filing Date is required.

☐ 4. The signature(s) to the oath or declaration is/are by a person other than inventor or person qualified under 37 CFR 1.42, 1.43 or 1.47.
A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

☐ 5. The signature of the following joint inventor(s) is missing from the oath or declaration:

_____

An oath or declaration in compliance with 37 CFR 1.63 listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date, is required.

☐ 6. **A $50.00 processing fee is required since your check was returned without payment (37 CFR 1.21(m)).**

☐ 7. Your filing receipt was mailed in error because your check was returned without payment.

☐ 8. The application was filed in a language other than English.
Applicant must file a verified English translation of the application, the $130.00 set forth in 37 CFR 1.17(k), unless previously submitted, and a statement that the translation is accurate (37 CFR 1.52(d)).

☐ 9. OTHER:_____

Direct the reply and any questions about this notice to "Attention: Box Missing Parts."

A copy of this notice MUST be returned with the reply.

Regina Fields
Customer Service Center
Initial Patent Examination Division (703) 308-1202

FORM PTO-1533 (REV. 8/98)

U.S. GPO: 1998-446-824

SAN00828249

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

#3

APPLICATION NUMBER	FILING/RECEIPT DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO./TITLE
09/348,536	07/07/99	BUCH-RASMUSSEN	T 5637.200-US

0242/0805

STEVE T ZELSON ESQ
NOVO NORDISK OF NORTH AMERICA INC
405 LEXINGTON AVENUE SUITE 6400
NEW YORK NY 10174-6401

NOT ASSIGNED

3734

DATE MAILED: 08/05/99

NOTICE TO FILE MISSING PARTS OF APPLICATION
Filing Date Granted

An Application Number and Filing Date have been assigned to this application. The items indicated below, however, are missing. Applicant is given TWO MONTHS FROM THE DATE OF THIS NOTICE within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). **If any of items 1 or 3 through 5 are indicated as missing, the SURCHARGE set forth in 37 CFR 1.16(e) of ☐ $65.00 for a small entity in compliance with 37 CFR 1.27, or ☐ $130.00 for a non-small entity, must also be timely submitted in reply to this NOTICE to avoid abandonment.**

If all required items on this form are filed within the period set above, the total amount owed by applicant as a ☐ small entity (statement filed) ☐ non-small entity is $ 130.00.

☐ 1. The statutory basic filing fee is:
- ☐ missing.
- ☐ insufficient.

Applicant must submit $_____ to complete the basic filing fee and/or file a small entity statement claiming such status (37 CFR 1.27).

☐ 2. The following additional claims fees are due:

$_____ for _____ total claims over 20.

$_____ for _____ independent claims over 3.

$_____ for multiple dependent claim surcharge.

Applicant must either submit the additional claim fees or cancel additional claims for which fees are due.

☑ 3. The oath or declaration:
- ☑ is missing or unsigned.
- ☐ does not cover the newly submitted items.

An oath or declaration in compliance with 37 CFR 1.63, including residence information and identifying the application by the above Application Number and Filing Date is required.

☐ 4. The signature(s) to the oath or declaration is/are by a person other than inventor or person qualified under 37 CFR 1.42, 1.43 or 1.47.
A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.

☐ 5. The signature of the following joint inventor(s) is missing from the oath or declaration:

An oath or declaration in compliance with 37 CFR 1.63 listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date, is required.

☐ 6. **A $50.00 processing fee is required since your check was returned without payment (37 CFR 1.21(m)).**

☐ 7. Your filing receipt was mailed in error because your check was returned without payment.

☐ 8. The application was filed in a language other than English.
Applicant must file a verified English translation of the application, the $130.00 set forth in 37 CFR 1.17(k), unless previously submitted, and a statement that the translation is accurate (37 CFR 1.52(d)).

☐ 9. OTHER:

Direct the reply and any questions about this notice to "Attention: Box Missing Parts."

A copy of this notice MUST be returned with the reply.

Regina Fields
Customer Service Center
Initial Patent Examination Division (703) 308-1202

09348536 141447 00000034 130.00 CH
10/14/1999 TLUU11 01 FC:105

FORM PTO-1533 (REV. 9/98) U.S. GPO. 1998-[illegible]

PART 2 - COPY TO BE RETURNED WITH RESPONSE

SAN00828250

COMBINED DECLARATION FOR PA[illegible] / APPLICATION AND POWER OF ATTORN[illegible]
(Includes Reference to PCT International Applications)

Attorney's Docket Number: 5637.200-US

#3

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Medication Delivery Device

the specification of which (check only one item below):

[ ] is attached hereto

[X] was filed as United States application

Application No. to be assigned

on July 7, 1999

and was amended

on _____

[ ] was filed as PCT international application

Number _____

on _____

and was amended under PCT Article 19

on _____

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim priority benefits under Title 35, United States Code, §119 of any provisional or foreign applications(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign applications(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR U.S. PROVISONAL/FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (if PCT, indicate "PCT")	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
Denmark	PA 1998 00909	July 8, 1998	[X] YES [ ] NO
Denmark	PA 1998 01500	November 17, 1998	[X] YES [ ] NO
USA	60/098,702	September 1, 1998	[X] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO
			[ ] YES [ ] NO

COMBINED DECLARATION FOR PA[illegible] APPLICATION AND POWER OF ATTORN
(Includes Reference to PCT International Applications)

Attorney's Docket Number: 3637.200-US

I hereby claim the benefit under Title 35, United States Code §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this applications is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S. APPLICATIONS		STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	Patented	Pending	Abandoned

PCT APPLICATIONS DESIGNATING THE U.S.					
APPLICATION NO.	FILING DATE	US SERIAL NUMBERS ASSIGNED (if any)			

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Steve T. Zelson Reg. No. 30,335 | Elias J. Lambiris Reg. No. 33,728 | Valeta A. Gregg Reg. No. 35,127 | Carol E. Rozek Reg. No. 36,993 | Robert L. Starnes Reg. No. 41,324 | Reza Green Reg. No. 38,475

Send Correspondence to: Steve T. Zelson, Esq.
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, New York 10174-6400

Direct Telephone Calls To:
Steve T. Zelson
(212) 867-0123

		Family Name	First Given Name	Second Given Name
1	Full Name of Inventor	Buch-Rasmussen	Thomas	
	Residence & Citizenship	City: DK-2820 Gentofte	State or Foreign Country: Denmark	Country of Citizenship: Denmark
	Post Office Address	Post Office Address: Dalvej 28	City: DK-2820 Gentofte	State & Zip Code/Country: Denmark
2	Full Name of Inventor	Family Name: Munk	First Given Name: Benny	Second Given Name:
	Residence & Citizenship	City: DK-2650 Hvidorre	State or Foreign Country: Denmark	Country of Citizenship: Denmark
	Post Office Address	Post Office Address: Bjæverskov Allé 52	City: DK-2720 Vanløse	State & Zip Code/Country: Denmark
3	Full Name of Inventor	Family Name: Poulsen	First Given Name: Jens	Second Given Name: Ulrik
	Residence & Citizenship	City: DK-2830 Virum	State or Foreign Country: Denmark	Country of Citizenship: Denmark
	Post Office Address	Post Office Address: Virumgade 54 C	City: DK-2830 Virum	State & Zip Code/Country: Denmark
4	Full Name of Inventor	Family Name: Ljungreen	First Given Name: Henrik	Second Given Name:
	Residence & Citizenship	City: DK-2750 Ballerup	State or Foreign Country: Denmark	Country of Citizenship: Denmark
	Post Office Address	Post Office Address: Jonstrupvej 244A	City: DK-2750 Ballerup	State & Zip Code/Country: Denmark

COMBINED DECLARATION FOR PA[illegible] APPLICATION AND POWER OF ATTORN. (Includes Reference to PCT International Applications)

Attorney's Docket Number: 5637.200-US

5	Full Name of Inventor	Family Name: Jensen	First Given Name: Peter	Second Given Name: Møller
	Residence & Citizenship	City: D-2970 Hørsholm	State or Foreign Country: Denmark	Country of Citizenship: Denmark
	Post Office Address	Post Office Address: Svenstrupvej 6	City: D-2970 Hørsholm	State & Zip Code/Country: Denmark
6	Full Name of Inventor	Family Name: Jensen	First Given Name: Jens	Second Given Name: Møller
	Residence & Citizenship	City: DK-1051 Copenhagen K	State or Foreign Country: Denmark	Country of Citizenship: Denmark
	Post Office Address	Post Office Address: Nyhavn 37	City: DK-1051 Copenhagen K	State & Zip Code/Country: Denmark
7	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country
8	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country
9	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address	Post Office Address	City	State & Zip Code/Country

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature of Inventor 5	Signature of Inventor 6	Signature of Inventor 7
Date: 2/8-99	Date: 16/8-99	Date: 5-8-99
Signature of Inventor 8	Signature of Inventor 9	Signature of Inventor 10
Date: 18/8-99	Date: 23/8-99	Date
Signature of Inventor 11	Signature of Inventor 12	Signature of Inventor 13
Date	Date	Date

Attorney Docket No.: 5637.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Rasmussen et al.

Serial No.: 09/348,536 Group Art Unit: 3734

Filed: July 7, 1999 Examiner: TBA

For: Medication Delivery Device

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Response to Notice to File Missing Parts (in duplicate)
2. Copy of Notice to File Missing Parts
3. Executed Combined Declaration and Power of Attorney

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

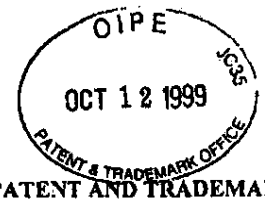
Commissioner of Patents and Trademarks
Washington, DC 20231

on October 5, 1999.

Miriam Kelly

(signature of person mailing paper)

Attorney Docket No.: 5637.200-US



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Rasmussen et al.

Serial No.: 09/348,536 Group Art Unit: 3734

Filed: July 7, 1999 Examiner: TBA

For: Medication Delivery Device

RESPONSE TO NOTICE TO FILE MISSING PARTS

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

In response to the Notice to File Missing Parts dated August 5, 1999 (a copy thereof is attached hereto), Applicants submit the Combined Declaration and Power of Attorney signed and dated by Applicants for the above-captioned application.

Please charge the required fee, estimated to be $130.00, to Novo Nordisk of North America, Inc., Deposit Account No. 14-1447. Please credit any overpayment to Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,

Date: October 5, 1999

Carol E. Rozek

Carol E. Rozek, Reg. No. 36,993
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

Attorney Docket No.: 5637.200-US

PATENT

#4 Ref

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

FILING UNDER 37 C.F.R. 1.53(b)

Box Patent Application
Assistant Commissioner for Patents
Washington, DC 20231

Express Mail Label No. EL293688877US
Date of Deposit July 7, 1999

Sir:

This is a request for filing an application under 37 C.F.R. 1.53(b) of

Applicant(s): Buch-Rasmussen et al.

Title: **Medication Delivery Device**

13 pages of specification 2 sheets of formal drawings

3 sheets of Declaration and Power of Attorney

[x] The filing fee is calculated as follows:

Basic Fee:	$ 760.00
Total Claims: 25 - 20 = 5 x 18 =	$ 90.00
Independent Claims: 2 - 3 = 0 x 78 =	$ 0.00
Total Fee:	$ 850.00

Priority of Danish application nos. PA 1998 00909 filed on July 8, 1998 and PA 1998 01500 filed on November 17, 1998 are claimed under 35 U.S.C. 119. Certified copies are submitted herewith.

Priority of U.S. provisional application no. 60/098,702 filed on September 1, 1998 are claimed under 35 U.S.C. 119.

--CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. 119 of Danish application serial nos. PA 1998 00909 filed July 8, 1998, PA 1998 01500 filed November 17, 1998, and U.S. Provisonal application serial no. 60/098,702 filed September 1, 1998, the contents of which are fully incorporated herein by reference.--

Address all future communications to Steve T. Zelson, Esq., Novo Nordisk of North America, Inc., 405 Lexington Avenue, Suite 6400, New York, NY 10174-6401.

Please charge the required fee, estimated to be $850, to Novo Nordisk of North America, Inc., Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,

Date: July 7, 1999

Carol E. Rozek, Reg. No. 36,993
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

Attorney Docket No.: 5637.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#5 ReB

In re Application of: Rasmussen et al.

Application No.: TBA Group Art Unit: TBA

Filed: July 7, 1999 Examiner: TBA

For: Medication Delivery Device

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Before the above-captioned application is taken up for examination, entry of the following amendment is respectfully requested:

IN THE SPECIFICATION:

At page 1, before the first line, insert the title: --Medication Delivery Device--.

At page 1, after the title, insert:

--CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. 119 of Danish application nos. PA 1998 00909 filed July 8, 1998 and PA 1998 01500 filed November 17, 1998, and U.S. provisional application no. 60/098,702 filed September 1, 1998, the contents of which are fully incorporated herein by reference.

IN THE CLAIMS:

Claim 2, line 1, first word, change "A" to --The--.

Claim 3, line 1, first word, change "A" to --The--.

Claim 4, line 1, first word, change "A" to --The--.

Claim 5, line 1, first word, change "A" to --The--.

Claim 6, line 1, first word, change "A" to --The--.

Claim 7, line 1, first word, change "A" to --The--.

Claim 8, line 1, first word, change "A" to --The--.

Claim 9, line 1, first word, change "A" to --The--.

Claim 10, line 1, first word, change "A" to --The--.

Claim 11, line 1, first word, change "A" to --The--.

Claim 12, line 1, first word, change "A" to --The--.

Claim 14, line 1, first word, change "A" to --The--.

Claim 15, line 1, first word, change "A" to --The--.

Claim 16, line 1, first word, change "A" to --The--.

Claim 17, line 1, first word, change "A" to --The--.

Claim 18, line 1, first word, change "A" to --The--.

Claim 19, line 1, first word, change "A" to --The--.

Claim 20, line 1, first word, change "A" to --The--.

Claim 21, line 1, first word, change "A" to --The--.

Claim 22, line 1, first word, change "A" to --The--.

Claim 23, line 1, first word, change "A" to --The--.

Claim 24, line 1, first word, change "A" to --The--.

Claim 25, line 1, first word, change "A" to --The--.

REMARKS

This amendment is submitted solely to correct the article "A" to "The" in the dependent claims. Since no new matter was been introduced by this amendment, entry of the amendment is respectfully requested.

Respectfully submitted,

Date: July 7, 1999

Carol E. Rozek, Reg. No. 36,993
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

UNITED STATES DE. ..TMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/340,536	07/07/99	BUCH-RASMUSSEN	T 5637.200-US

EXAMINER
SIRMONS, K.

ART UNIT	PAPER NUMBER
3763	6

DATE MAILED: 03/09/00

GM12/0309

STEVE T ZELSON ESQ
NOVO NORDISK OF NORTH AMERICA INC
405 LEXINGTON AVENUE SUITE 6400
NEW YORK NY 10174-6401

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/86)

1- File Copy

Office Action Summary

Application No.	Applicant(s)
09/348,536	Thomas Bush-Rasmussen et al
Examiner	**Group Art Unit**
Kevin C. Simmons	3783

[X] Responsive to communication(s) filed on Jul 7, 1999

[ ] This action is FINAL.

[ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

[X] Claim(s) 1-25 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

[ ] Claim(s) _____ is/are allowed.

[ ] Claim(s) _____ is/are rejected.

[ ] Claim(s) _____ is/are objected to.

[X] Claims 1-25 are subject to restriction or election requirement.

Application Papers

[ ] See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

[ ] The drawing(s) filed on _____ is/are objected to by the Examiner.

[ ] The proposed drawing correction, filed on _____ is [ ] approved [ ] disapproved.

[ ] The specification is objected to by the Examiner.

[ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

[ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

[ ] All [ ] Some* [X] None of the CERTIFIED copies of the priority documents have been

[ ] received.

[ ] received in Application No. (Series Code/Serial Number) _____.

[ ] received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

[ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

[ ] Notice of References Cited, PTO-892

[ ] Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

[ ] Interview Summary, PTO-413

[ ] Notice of Draftsperson's Patent Drawing Review, PTO-948

[ ] Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-12 are, drawn to medication device, classified in class 604, subclass 232

   II. Claims 13-25 are, drawn to a cartridge assembly, classified in class 604, subclass 232.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as a valve and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. A telephone call was made to Carol E. Rozek on 2/2/00 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703)306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

If attempt to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wynn Wood Coggins, can be reached on (703) 308-1344.

/KCS

Kevin C. Sirmons

Patent Examiner

2/2/00

WYNN WOOD COGGINS
SUPERVISORY PATENT EXAMINER

Attorney Docket No.: 5637.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/348,536 Group Art Unit: 3763

Filed: July 7, 1999 Examiner: K. Sirmons

For: Medication Delivery Device

CERTIFICATE OF FACSIMILE TRANSMISSION

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Response to Restriction Requirement

was sent to the United States Patent Office by telefax to the attention of Examiner K. Sirmons, fax number (703) 305-3704.

Respectfully submitted,

Date: April 4, 2000

Miriam Kelly
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

Attorney Docket No.: 5637.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Application No.: 09/348,536 Group Art Unit: 3763

Filed: July 7, 1999 Examiner: K. Simmons

For: Medication Delivery Device

RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

This paper is being filed in response to the Office Action mailed March 9, 2000 wherein the Examiner requested Applicants to elect one of two (2) designated groups.

In response to this requirement, Applicants hereby elect with traverse the invention of Group I (claims 1-12), drawn to a medication device. Applicants hereby reserve the right to file a continuing application directed to the nonelected subject matter.

The basis for traverse is that there would not be a serious burden on the examiner if restriction were not required. Each of the two designated inventions is classified in Class 604, subclass 232.

The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this response or application.

Respectfully submitted,

Date: April 4, 2000

Carol E. Rozek, Reg. No. 36,993
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

APR. 4.2000 10:11AM NNNA NO.957 P.1/3

RESTRICTION ELECTION FACSIMILE TRANSMISSION

FAX RECEIVED
APR 4 2000
GROUP 1600

DATE: April 4, 2000

FROM/ATTORNEY: Carol Rozek, Esq.

FIRM: Novo Nordisk of No. America

PAGES, INCLUDING COVERSHEET: 3

PHONE NUMBER: (212) 878-9648

TO EXAMINER: K. Simmons, GAU 3763

SERIAL NUMBER: 09/344,536

FAX/TELECOPIER NUMBER: (703) 305-3704

RECEIVED
APR -6 2000
TC 2600 MAIL ROOM
RECEIVED
APR -7 2000
GROUP 3700

PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY FOR RESPONSES TO RESTRICTIONS.

COMMENTS: See attached.

IF YOU HAVE NOT RECEIVED ALL THE PAGES OF THIS TRANSMISSION, PLEASE CONTACT THE ATTORNEY AT THE TELEPHONE NUMBER LISTED ABOVE.

IN COMPLIANCE WITH 1096 OG 30, THE FILING DATE ACCORDED EACH OFFICIAL FAX TRANSMISSION WILL BE DETERMINED BY THE FAX MACHINE DATE STAMP FOUND ON THE LAST PAGE OF THE TRANSMISSION, UNLESS THAT DATE IS A SATURDAY, SUNDAY, OR FEDERAL HOLIDAY WITHIN THE DISTRICT OF COLUMBIA, IN WHICH CASE THE OFFICIAL DATE OF RECEIPT WILL BE THE NEXT BUSINESS DAY.

C:\dontpurgFax_File

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/348,536	07/07/99	BUCH-RASMUSSEN T	5637.200-US

QM32/0426

STEVE T ZELSON ESQ
NOVO NORDISK OF NORTH AMERICA INC
405 LEXINGTON AVENUE SUITE 6400
NEW YORK NY 10174-6401

EXAMINER	
SIRMONS,K	
ART UNIT	**PAPER NUMBER**
3763	8

DATE MAILED: 04/26/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

1- File Copy

Office Action Summary

Application No.	Applicant(s)
09/348,536	Thomas Bush-Rasmussen et al
Examiner	**Group Art Unit**
Kevin C. Sirmons	3763

[X] Responsive to communication(s) filed on *Jul 7, 1999*

[ ] This action is **FINAL.**

[ ] Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

[X] Claim(s) *1-25* is/are pending in the applicat

Of the above, claim(s) *13-25* is/are withdrawn from consideration

[ ] Claim(s) _____ is/are allowed.

[X] Claim(s) *1-12* is/are rejected

[ ] Claim(s) _____ is/are objected to.

[ ] Claims _____ are subject to restriction or election requirement

Application Papers

[X] See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948

[ ] The drawing(s) filed on _____ is/are objected to by the Examiner.

[ ] The proposed drawing correction, filed on _____ is [ ] approved [ ] disapproved

[ ] The specification is objected to by the Examiner.

[ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

[ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

[ ] All [ ] Some* [X] None of the CERTIFIED copies of the priority documents have been

[ ] received.

[ ] received in Application No. (Series Code/Serial Number) _____.

[ ] received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

[ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

[X] Notice of References Cited, PTO-892

[ ] Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

[ ] Interview Summary, PTO-413

[X] Notice of Draftsperson's Patent Drawing Review, PTO-948

[ ] Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of group I in Paper No. 7 is acknowledged. The traversal is on the ground(s) that there would not be a serious burden on the examiner if restriction were not required. This is not found persuasive because group one also requires a search in 604/ 200, 201, 228, and 232-234. Furthermore, the search required for group one is not required for group II. In addition, group II is deemed useful as a valve and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the reinforcements, a cartridge housing, and a cross-section of the cartridge that is non-circular must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1, it is unclear if the applicant is claiming a needle assembly.

5. Claim 8 recites the limitation "reinforcements", "the cartridge wall", and claim 11 recites the limitation "the cross-section." There is insufficient antecedent basis for this limitation in the claim.

As to claim 9, it is unclear what the applicant considers the cartridge housing.

As to claim 11, it is unclear what the applicant considers to be the cross-section of the cartridge because it appears to be circular.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-9, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Reynolds US Pat No. 5,364,369.

Reynolds discloses a medication delivery device comprising: a cartridge assembly (6), a dosing assembly (B) and optionally a needle assembly (2); said cartridge assembly having one end sealed with a pierceable sealing (5), said end of the cartridge assembly comprising coupling means for engaging a needle assembly (cartridge assembly engages the needle assembly forming a coupling means), and another end comprising coupling means for engaging the dosing assembly (18); said cartridge assembly further comprising a cartridge (6), wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge (4 and 5 are also considered by the examiner to be moulded coupling means with the cartridge), the cartridge further comprising a stopper (8) adapted to receive plunger means (10 and/or 14, it is the examiner's position that 10 and/or 14 are considered plunger means), and said dosing assembly comprising plunger means having coupling means for engaging the cartridge (note: (8) is a part of the cartridge (6), therefore, (10/14) which are considered the plunger means engages the cartridge (6)), and said plunger means is adapted to engage the stopper of the cartridge when the dosing assembly is coupled to the cartridge (figs. 1 and 2); wherein all the coupling means of the cartridge assembly are unitarily moulded with the cartridge (note:(8) is a part of the cartridge (6) which is considered one part, therefore, they are moulded; wherein at least one coupling means of the cartridge is an external coupling (4 and 5); wherein at least one coupling means of the cartridge is a threaded coupling (18); wherein the coupling means for engaging to dosing means is an external threaded coupling (8); wherein the cartridge is moulded of a plastic material (col. 10, lines 43-58); wherein the cartridge is at least partly transparent (col. 10, lines 43-58);

wherein reinforcements of the cartridge wall are integrally moulded with the cartridge (7, col. 2, lines 49-61); wherein the cartridge further comprises a cartridge housing (6); wherein the coupling means of the cartridge are opposed each other (figs. 1 and 2).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reynolds U.S. Pat. No. 5,364,369 in view of Sams U.S. Pat. No. 4,865,591.

Reynolds discloses a medication delivery device substantially as claimed except for: wherein the cartridge further comprise a scale. However, Sams discloses a cartridge with a scale. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cartridge of Reynolds using the scale as taught by Sams, since Sams discloses that the scale will indicate to the user the amount of dosage selected for injection.

Conclusion

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703)306-5410.

The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

If attempt to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wynn Wood Coggins, can be reached on (703) 308-1344.

KCS

Kevin C. Sirmons

Patent Examiner

4/21/00

WYNN WOOD COGGINS
SUPERVISORY PATENT EXAMINER

FORM PTO-892	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	SERIAL NO.	GROUP ART UNIT	ATTACHMENT TO PAPER NO.	
	NOTICE OF REFERENCES CITED	09348536	3763		8
		APPLICANT(S) Bucj-Rasmussen			

U.S. PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	A	5,364,369	11/1994	Reynolds	604	187	
	B	4,865,591	9/1989	Sams	604	186	
	C	5,554,125	9/1996	Reynolds	604	187	
	D	5,137,511	8/1992	Reynolds	604	88	
	E	4,597,753	7/1986	Turley	604	61	
	F						
	G						
	H						
	I						
	J						
	K						

FOREIGN PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS
	L						
	M						
	N						
	O						
	P						
	Q						

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	R	
	S	
	T	
	U	

EXAMINER	DATE	
Kevin C. Sirmons	April 21, 2000	Form892ccs2106b

* A copy of this reference is not being furnished with this office action.
(See Manual of Patent Examining Procedure, section 707.05(a).)

Attorney Docket No.: 5637.200-US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Application No.: 09/348,536 Group Art Unit: 3734

Filed: July 7, 1999 Examiner: To be assigned

For: Medication Delivery Device

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, DC 20231

#9 AMB 6/12/00

Sir:

In accordance with 37 C.F.R. 1.56, 1.97 and 1.98, Applicants submit herewith references which they believe may be material to the patentability of this application and with respect to which there may be a duty to disclose in accordance with 37 C.F.R. 1.56.

While the references may be "material" under 37 C.F.R. 1.56, it is not intended to constitute an admission that the references are "prior art" unless specifically designated as such.

The filing of this Information Disclosure Statement shall not be construed as a representation that no other material references than those listed exist or that a search has been conducted.

The references are listed in PTO form 1449 which is in accordance with the requirements of M.P.E.P. 609. A copy of the references is also enclosed. The references are as follows:

1. EP 0 688 571
2. U.S. 4,936,833
3. U.S. 5,226,895
4. U.S. 5,549,575
5. U.S. 5,688,251
6. WO 95/13842

7. WO 94/21213
8. WO 97/49620
9. WO 96/02290
10. U.S. 4,973,318

It is respectfully requested that these references be considered by the Patent and Trademark Office in its examination of the above-identified application and be made of record therein. The Examiner is also invited to contact the Undersigned if there are any questions concerning this paper or the attached references.

Respectfully submitted,

Date: January 26, 2000

Carol E. Rozek, Reg. No. 36,993
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

FORM 19 (Rev. 10/88)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use several sheets if necessary)

Atty. Docket No. 5637.200-US | Serial No. 09/348,536

Applicant Buch-Rasmussen et al.

Filing Date July 7, 1999 | Group 3734

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
KCS		4,936,833	6/26/90	Sams			
		5,226,895	7/13/93	Harris			
		5,549,575	8/27/96	Giambattista et al.			
		5,688,251	11/18/97	Chanoch			
		4,973,318	11/27/90	Holm et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
KCS		EP 0 688 571	12/27/95	EPO				
		WO 95/13842	5/26/95	WIPO				
		WO 94/21213	9/29/94	WIPO				
		WO 97/49620	12/31/97	WIPO				
		WO 96/02290	2/1/96	WIPO				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER Simmons | DATE CONSIDERED 1/9/01

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

GP 3734

Attorney Docket No.: 5637.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/348,536 Group Art Unit: 3734

Filed: July 7, 1999 Examiner: To be assigned

For: Medication Delivery Device

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Information Disclosure Statement
2. PTO-1449 Form
3. Copy of References

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner of Patents and Trademarks
Washington, DC 20231

on January 26, 2000.

Miriam Kelly
(name of person mailing paper)

Miriam Kelly
(signature of person mailing paper)

COPY

Attorney Docket No.: 5637.200-US

PATENT

#10

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/348,536 Group Art Unit: 3734

Filed: July 7, 1999 Examiner: To be assigned

For: Medication Delivery Device

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Request for Corrected Filing Receipt
2. Copy of Filing Receipt

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner of Patents and Trademarks
Washington, DC 20231

on January 21, 2000.

Carol McFarlane
(name of person mailing paper)

Carol McFarlane
(signature of person mailing paper)

Attorney Docket No.: 5637.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/348,536 Group Art Unit: 3734

Filed: July 7, 1999 Examiner: TBA

For: Medication Delivery Device

REQUEST FOR CORRECTED FILING RECEIPT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Applicants filed the above-captioned application on July 7, 1999.

The filing receipt received by Applicants incorrectly indicates the city of residence for inventor Munk as Hvidorre. The correct city of residence is Vanlose. A copy of the filing receipt is attached to this request.

Applicants therefore request the issuance of a corrected filing receipt with the correct city of residence.

Applicants submit that the error was the fault of the USPTO. Therefore, a fee for this service is not required.

Respectfully submitted,

Date: January 21, 2000

Carol E. Rozek

Carol E. Rozek, Reg. No. 36,993
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

PTO-103X
(Rev. 6-99)

FILING RECEIPT

CORRECTED

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTORNEY DOCKET NO.	DRWGS	TOT CL	IND CL
09/348,536	07/07/99	3734	$980.00	5637.200-US	2	25	2

STEVE T ZELSON ESQ
NOVO NORDISK OF NORTH AMERICA INC
405 LEXINGTON AVENUE SUITE 6400
NEW YORK NY 10174-6401

OIPE JC82 SEC JAN 31 2000 PATENT & TRADEMARK OFFICE

NOV 29 1999

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts of Application" ("Missing Parts Notice") in this application, please submit any corrections to this Filing Receipt with your reply to the "Missing Parts Notice." When the PTO processes the reply to the "Missing Parts Notice," the PTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s) THOMAS BUCH-RASMUSSEN, GENTOFTE, DENMARK; BENNY MUNK, HVIDORRE, DENMARK; JENS ULRIK POULSEN, VIRUM, DENMARK; HENRIK LJUNGREEN, BALLERUP, DENMARK; PETER MOLLER JENSEN, HORSHOLM, DENMARK; JENS MOLLER JENSEN, COPENHAGEN K, DENMARK.

CONTINUING DATA AS CLAIMED BY APPLICANT-
PROVISIONAL APPLICATION NO. 60/098,702 09/01/98

FOREIGN APPLICATIONS- DENMARK PA 1998 00909 07/08/98
DENMARK PA 1998 01500 11/17/98

IF REQUIRED, FOREIGN FILING LICENSE GRANTED 08/03/99
TITLE
MEDICATION DELIVERY DEVICE

PRELIMINARY CLASS: 604

DATA ENTRY BY: PERRY, REGINA TEAM: 02 DATE: 11/18/99

SAN00828283

GAU 3763

Docket No. 5637.200-US

SKADDEN, ARPS, SLATE, MEAGHER & FLOM
Four Times Square
New York, NY 10036-6522

Telephone: (212) 735-3020
Facsimile: (917) 777-3020

Date: October 25, 2000

Applicant(s)	:	Buch-Rasmussen et al.	
Serial No.	:	09/348,536	Examiner: Simons, K.
Filed	:	July 7, 1999	Art Unit: 3763
Title	:	Medication Delivery Device	

AMENDMENT TRANSMITTAL
AND REQUEST FOR EXTENSION OF TIME

Assistant Commissioner For Patents
Washington, DC 20231

Sir:

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on October 25, 2000.

Robert B. Smith — Reg. No. 28,538

Robert B. Smith — October 25, 2000
Signature — Date

Transmitted herewith is an Amendment in application.

1. ( ) No additional fee is required.

11/06/2000 EWILLIAM 00000001 192365 09348536

01 FC:117 890.00 CH

2. ( ) The fee has been calculated as shown below:

Claims remaining	Prior Paid Claims	Extra	Rate	Fee
Total:	minus (at least 20) =	@	$18	– $
Independent	minus (at least 3) =	@	$80	= $

TOTAL ADDITIONAL FEE: $

3. (X) An extension of time to respond to the PTO Communication dated April 26, 2000 is hereby requested. The required fee is indicated below:

Within first month:	( )	$110
Within second month	( )	$390
Within third month	(X)	$890
Within fourth month	( )	$1,390

4. ( ) The Amendment includes an Information Disclosure Statement. Enclosed is Form PTO-1449 and copies of _____ reference(s).

5. (X) The Commissioner is hereby authorized to charge the amount of $ 890.00 representing (a) additional claims fee ($); (b) the extension fee ($ 890); and (c) the fee for filing an Information Disclosure Statement ($) to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.

6. (X) In the event that an extension of time is required and applicant has inadvertently overlooked the need to request a petition and file the fee, the applicant hereby petitions for such extension of time. The Commissioner is authorized to charge the required fee to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.

7. (X) The Commissioner is hereby authorized to charge payment of any additional fees required in connection with this application, and credit any overpayment, to deposit account No. 19-2385. A copy of this sheet is enclosed.

Skadden, Arps, Slate, Meagher & Flom

By Robert B. Smith

Robert B. Smith
Registration No. 28,538
Attorneys for Applicant(s)
(212) 735-3020

Docket No. 5637.200-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	Buch-Rasmussen et al.	
Serial No.	:	09/348,536	Examiner: Simons, K.
Filed	:	July 7, 1999	Art Unit: 3763
Title	:	Medication Delivery Device	

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on October 25, 2000.

Robert B. Smith Reg. No. 28,538

Robert B. Smith October 25, 2000
Signature Date

October 25, 2000

AMENDMENT

Assistant Commissioner For Patents
Washington, DC 20231

Sir:

In response to the Office Action dated April 26, 2000, please amend the application as indicated below.

IN THE SPECIFICATION:

On page 1, line 23, change "displaced" to - - replaced - -;

On page 2, line 7, change "minimised" to - - minimized - -; and

on line 27, change "coupling(s) secure(s)" to - - coupling or couplings ensure - -;

On page 3, line 11, change "as to secure" to - - so as to ensure - -; and

On page 9, line 21, change "effect" to - - cause - -.

IN THE CLAIMS:

Please cancel claim 1 and substitute the following claim therefor:

- - 26. A medication delivery device comprising a cartridge assembly having opposite ends, and a dosing assembly for setting a desired dose and acting on said cartridge assembly to cause such dose to be delivered,

wherein said cartridge assembly includes a molded cartridge and a stopper disposed in said cartridge, wherein one end of said cartridge assembly is sealed with a pierceable sealing, wherein said one end includes a first coupling means for releasably mounting a needle assembly having a skin-piercing needle, and wherein the other end of said cartridge assembly includes a second coupling means for engaging said dosing assembly, wherein at least one of said coupling means is unitarily molded with the cartridge, and

wherein said dosing assembly includes a housing, a plunger, and a mechanism for setting a desired dose and for moving said plunger, relative to said housing, in an axial direction for administering a set dose, and wherein said dosing assembly housing includes a coupling member for engaging said second coupling means of said cartridge assembly for securing said housing against axial movement relative to said cartridge assembly and such that said plunger engages said stopper for moving said stopper in response to plunger movement. - -

Rewrite claims 2-6 as follows:

- - 2. (Twice Amended) The medication delivery device according to claim [1] 26, wherein [all the] both said coupling means of [the] said cartridge assembly are unitarily [moulded] molded with the cartridge.

3. (Twice Amended) The medication delivery device according to claim [1] 26, wherein the said at least one coupling means of [the] said cartridge assembly is an external coupling.

4. (Twice Amended) The medication delivery device according to claim [1] 26, wherein the said at least one coupling means of [the] said cartridge assembly is a threaded coupling.

5. (Twice Amended) The medication delivery device according to claim 4, wherein [the] said second coupling means [for engaging to dosing means] is an external threaded coupling.

~~4.~~ 6. (Twice Amended) The medication delivery device according to claim [1] ~~20~~, wherein the cartridge is [moulded] molded of a plastic material. - -

Cancel claims 8-9 and 11 without prejudice.

Rewrite claims 10 and 12 as follows:

- - ~~10.~~ 9. (Twice Amended) The medication delivery device according to claim [1] ~~26~~, wherein the [cartridge] dosing assembly further comprises a scale.

~~12.~~ 11. (Twice Amended) The medication delivery device according to claim [1] ~~26~~, wherein the coupling means of the cartridge assembly are opposed [each to one another. - -

Cancel non-elected claims 13-25 without prejudice.

Add the following claims:

- - 27. The medication delivery device according to claim 26, wherein the said at least one coupling means is said second coupling means.

15

28. The medication delivery device according to claim 27, wherein said second coupling means is a threaded coupling. - -

C5

REMARKS

By the foregoing amendments, the specification has been amended to make several idiomatic revisions. Also, as discussed further below, claim 1 has been cancelled, and new claim 26 is submitted, to overcome the formal rejection raised to claim 1 and to define, with greater particularity, the novel features of the invention.

The applicants note that the restriction requirement has been made final, and have canceled non-elected claims 13-25 without prejudice to filing a divisional application.

In paragraph 2 of the April 26, 2000 Office Action, the Examiner objects under Rule 83(a) to the drawings because the reinforcements, cartridge housing, and non-circular cartridge cross-sections recited in dependent claims 8, 9, and 11 are not shown in the drawings. Because such features are covered generically in other claims, and to advance the prosecution of the present application, the applicants have merely canceled such claims rather than amend the drawings. Applicants have canceled such claims, however, without prejudice to reintroducing

such claims, with corresponding drawing amendments, at a future time if deemed appropriate.

In paragraphs 3-5 of the Office Action, the Examiner raises certain formal rejections as to the language of claims 1, 8, 9, and 11. As noted above, claims 8-9 and 11 have been canceled. With respect to claim 1, the Examiner rejected such claim under 35 U.S.C. § 112, second paragraph, on the grounds that it was not clear whether the applicants were claiming the needle assembly per se. Claim 1 has been rewritten as new claim 26, where it is clear that, while the claimed device includes a fitting for receiving a needle assembly, the needle assembly per se is not part of the claimed device.

Original claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by Reynolds U.S. patent No. 5,364,369. Reynolds discloses, in Figure 6, a medication delivery device adapted for an injection needle. The Reynolds device includes a cartridge (mis-labeled "8" in Figure 6), which Reynolds refers to as a vial, having a stopper 8 (the stopper is not labeled in Figure 6), and a plunger 10 which can push the stopper 8 forward to expel a dose of medicine through the needle 28. The forward end of Reynold's syringe includes a pierceable membrane 5. An outer cap 2, having a needle 22 to pierce the membrane 5, can be mounted on the forward end of the cartridge 6. In turn, a needle assembly, with a skin-piercing needle 28, can be mounted on the outer cap 2.

As shown in other figures, when the Reynold's cartridge 6 holds only one part of a medicament mixture, prior to using the syringe, a capsule 14 containing the other ingredient, i.e., a liquid, and a cap 12, are pressed into the bore of the plunger 10. A needle 44 on the cap 12 allows the liquid in the capsule 14 to enter the bore of the cartridge 6 and mix with the dry medicament. The capsule 14 and cap 12 are then removed, in preparation for using the syringe (see Fig. 5).

New claim 26 recites a medication delivery device comprising a cartridge assembly and a dosing assembly for setting and administering a desired dose. The cartridge assembly includes a molded cartridge. Opposite ends of the cartridge assembly include first and second coupling means for engaging a needle assembly having a skin-piercing needle and the dosing assembly, respectively. At least one of the coupling means is molded unitarily with the cartridge.

Claim 26 further recites that the dosing assembly includes a housing, a plunger, and a mechanism for setting a desired dose and for moving the plunger, relative to the housing, in an axial direction for administering a set dose. Also, the housing includes a coupling member, e.g., threads, for engaging the second coupling means of the cartridge assembly so as to secure the housing against axial movement relative to the cartridge assembly and such that the plunger engages the stopper. In such manner, when the dosing assembly moves the plunger, the plunger moves the stopper forward to eject the set dose.

As noted above, claim 26 recites that at least one of the two coupling means on the cartridge assembly is molded integrally with the cartridge itself. Reynolds discloses a means at its forward end for mounting a needle assembly with a skin-piercing needle 28, but such means is the cap 2. The cap 2 and cartridge 6 are separate parts, and thus Reynolds does not have the recited integrally molded coupling means at its forward end.

Reynolds also lacks any dosing assembly as now defined in claim 26. In particular, Reynolds does not have any mechanism to set a dose and to move a plunger to administer the set dose. Nor does Reynolds have a housing associated with its plunger or any coupling means which can secure the cartridge 6 and such a housing against relative axial movement.

For such reasons, the applicants respectfully submit that Reynolds neither anticipates nor suggests the invention as recited in claim 26, and favorable consideration and allowance of new claim 26 are respectfully requested.

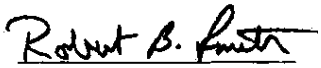
Claim 2 recites that both the recited couplings on cartridge assembly are molded integrally with the cartridge. As noted above, the needle coupling of the Reynolds cartridge is not molded integrally with its cartridge 6, and Reynolds lacks any coupling for a dosing assembly. Thus, allowance of claim 2 is respectfully requested for such additional reason.

New claim 27 recites that the said at least one coupling (i.e., the coupling which is molded integrally with the cartridge) is the second coupling, i.e., the coupling for engaging the dosing assembly housing. Claim 28 recites that this second coupling is a threaded coupling. As noted above, Reynolds has no coupling, as recited in claim 26, between the capsule 14 and the cartridge. For such reason, as well as other reasons recited in connection with claim 26, favorable consideration and allowance of claims 27-28 are respectfully requested.

With respect to the remaining dependent claims, favorable consideration and allowance of such claims are respectfully requested for the reasons recited in connection with claim 26.

In light of the foregoing amendments and remarks, favorable reconsideration and allowance of the application are respectfully requested.

Respectfully submitted,



Robert B. Smith
PTO Registration No. 28,538
Attorney for applicant(s)
(212) 735-3020

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/348,536	07/07/99	BUCH-RASMUSSEN T	5637.200-US

GN12/0117

STEVE T ZELSON ESQ
NOVO NORDISK OF NORTH AMERICA INC
405 LEXINGTON AVENUE SUITE 6400
NEW YORK NY 10174-6401

EXAMINER	
SIMMONS, K	
ART UNIT	**PAPER NUMBER**
3763	#13

DATE MAILED: 01/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/348,536	Applicant(s) Thomas Bush-Rasmussen et al
	Examiner Kevin C. Sirmons	Group Art Unit 3763

☒ Responsive to communication(s) filed on Oct 27, 2000

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 2-7, 10, 12, and 26-28 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 2-7, 10, 12, and 26-28 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> > (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

2. Claims 26-28, 2-5, 7 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Reynolds U.S. Pat. No. 6,146,361.

DiBiasi et al discloses a medication delivery device comprising: a cartridge assembly (22) having opposite ends, and a dosing assembly (38), wherein said cartridge assembly includes a molded cartridge (22) and a stopper disposed in said cartridge (36), wherein one end of said cartridge assembly is sealed with a pierceable sealing (32), wherein said one end includes a first coupling means for releasably mounting a needle assembly having a skin-piercing needle (88), and wherein the other end of said cartridge assembly includes a second coupling means for engaging said dosing assembly (13), wherein at least one of said coupling means is unitarily molded with the cartridge (13, 88), and wherein said dosing assembly includes a housing (38), plunger (distal end of 44), and a mechanism for setting a desired dose and for moving said plunger (col. 3, lines 20-23),

relative to said housing in an axial direction for administering a set dose (functional language), (fig. 1), and wherein said dosing assembly housing includes a coupling member (41) for engaging said second coupling means of said cartridge assembly (fig. 1); for securing said housing against axial movement relative to said cartridge assembly and such that said plunger engages said stopper for moving said stopper in response to plunger movement (fig.1); wherein both said coupling means of said cartridge assembly are unitarily molded with the cartridge (figs. 1 and 2); wherein the said at least one coupling means of said cartridge assembly is an external coupling (13, 88); wherein the said at least one coupling means of said cartridge assembly is a threaded coupling (13, 88), wherein said second coupling means is an external threaded coupling (13); wherein the coupling of the cartridge assembly are opposed (figs. 1 and 2); wherein the said at least one coupling means is said second coupling means (figs. 1 and 2); wherein said second coupling means is a threaded coupling (figs. 1 and 2); wherein the cartridge is at least partly transparent (figs. 1 and 2).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 6 and 10 are rejected under 35 U.S.C 103(a) as being unpatentable over DiBiasi et al U.S. Pat. No. 6,146,361 in view of Sams U.S. Par. No. 4,865,591.

DiBiasi discloses a medication delivery device substantially as claimed except for: wherein the dosing assembly further comprise a scale and wherein the cartridge is molded of a plastic material. However, Sams discloses a dosing assembly with a scale.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cartridge of DiBiasi using the scale as taught by Sams, since Sams discloses that the scale will indicate to the user the amount of dosage selected for injection. Furthermore, it would have been an obvious matter of design choice to mold the cartridge from a plastic material, since applicant has not disclosed that a molded plastic cartridge solves any stated problem or is form any particular purpose and it appears that the invention would perform equally well with glass.

Response to Arguments

5. Applicant's arguments with respect to claims 2-7, 10, 12, and 26-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703)306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

KCS

Kevin C. Sirmons

Patent Examiner

1/09/01

RICHARD K. SEIDEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

ATTACHMENT TO AND MODIFICATION OF NOTICE OF ALLOWABILITY (PTO-37)

(November, 2000)

NO EXTENSIONS OF TIME ARE PERMITTED TO FILE CORRECTED OR FORMAL DRAWINGS, OR A SUBSTITUTE OATH OR DECLARATION, notwithstanding any indication to the contrary in the attached Notice of Allowability (PTO-37).

If the following language appears on the attached Notice of Allowability, the portion lined through below is of no force and effect and is to be ignored[1]:

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE **THREE MONTHS** FROM THE "DATE MAILED" of this Office action. Failure to comply will result in ABANDONMENT of this application. ~~Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).~~

Similar language appearing in any attachments to the Notice of Allowability, such as in an Examiner's Amendment/Comment or in a Notice of Draftperson's Patent Drawing Review, PTO-948, is also to be ignored.

---

[1] The language which is crossed out is contrary to amended 37 CFR 1.85(c) and 1.136. See *"Changes to Implement the Patent Business Goals"*, 65 *Fed. Reg.* 54603, 54629, 54641, 54670, 54674 (September 8, 2000), 1238 *Off. Gaz. Pat. Office* 77, 99, 110, 135, 139 (September 19, 2000).

FORM PTO-892 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	SERIAL NO.	GROUP ART UNIT	ATTACHMENT TO PAPER NO.	
NOTICE OF REFERENCES CITED	09348536	3763		13
	APPLICANT(S) Buch-Rasmussen et al			

U.S. PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	A	6,146,361	11/2000	DiBiasi et al.	604	232	
	B						
	C						
	D						
	E						
	F						
	G						
	H						
	I						
	J						
	K						

FOREIGN PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUB-CLASS
	L						
	M						
	N						
	O						
	P						
	Q						

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	R	
	S	
	T	
	U	

EXAMINER	DATE	
Kevin C. Sirmons	January 10, 2001	Form892ccs2106b

* A copy of this reference is not being furnished with this office action.
(See Manual of Patent Examining Procedure, section 707.05(a).)

AF/3763 #
618
D3
#14

Docket No. 5637.200-US

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK 10036-6522
(212) 735-3000
FAX: (212) 735-2000

Applicant(s) :	Buch-Rasmussen et al.		
Serial No. :	09/348,536	Examiner: Simons, K.	
Filed :	July 7, 1999	Art Unit: 3763	
Title :	Medication Delivery Device		

AMENDMENT TRANSMITTAL
AND REQUEST FOR EXTENSION OF TIME

Date: June 11, 2001

Box AF
Assistant Commissioner For Patents
Washington, DC 20231

Sir:

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on June 11, 2001.

Robert B. Smith — Reg. No. 28,538

Robert B. Smith — June 11, 2001
Signature — Date

Transmitted herewith is an Amendment in the above-identified application.

1. ( ) No additional fee is required.

06/14/2001 GTEFFERA 00000138 192385 09348536
01 FC:116 390.00 CH

2. ( ) The fee has been calculated as shown below:

Claims remaining	Prior Paid Claims	Extra	Rate	Fee
Total:	minus (at least 20) =	@	$18	= $
Independent	minus (at least 3) =	@	$80	= $___
	TOTAL ADDITIONAL FEE: $			

3. (X) An extension of time to respond to the PTO Communication dated January 17, 2001 is hereby requested. The required fee is indicated below:

Within first month:	( )	$ 110
Within second month	(X)	$ 390
Within third month	( )	$ 890
Within fourth month	( )	$1,390
Within the fifth month	( )	$1,890

4. ( ) Enclosed please find a check in the amount of $ 0.00 representing (a) additional claims fee ($ 0) and (b) the extension fee ($ 0).

5. (X) The Commissioner is hereby authorized to charge the amount of $ 390.00 representing (a) additional claims fee ($); and (b) the extension fee ($ 890) to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.

6. (X) In the event that an extension of time is required and applicant has inadvertently overlooked the need to request a petition and file the fee, the applicant hereby petitions for such extension of time. The Commissioner is authorized to charge the required fee to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.

7. (X) The Commissioner is hereby authorized to charge payment of any additional fees required in connection with this application, and credit any overpayment, to deposit account No. 19-2385. A copy of this sheet is enclosed.

Skadden, Arps, Slate, Meagher & Flom

By Robert B. Smith

Robert B. Smith
Registration No. 28,538
Attorneys for Applicant(s)
(212) 735-3020

Docket No. 5637.200-US

DB 6-18

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	Buch-Rasmussen et al.	
Serial No.	:	09/348,536	Examiner: Simons, K.
Filed	:	July 7, 1999	Art Unit: 3763
Title	:	Medication Delivery Device	

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on June 11, 2001.

Robert B. Smith Reg. No. 28,538

Robert B. Smith
Signature

June 11, 2001
Date

June 11, 2001

RESPONSE AFTER FINAL REJECTION

Box AF
Assistant Commissioner For Patents
Washington, DC 20231

Sir:

The applicants respectfully request reconsideration of the final rejection of claims 2-7, 10-12, and 26-28, mailed on January 17, 2001, on the grounds, discussed further below, that the Dibiasi patent fails to disclose a syringe in which one of the two claimed coupling means are provided on the **cartridge** itself, as

recited in independent claim 26. In requesting reconsideration, the applicants rely upon the Examiner's own interpretation of Dibiasi, as set forth in the final rejection.

More particularly, claim 26 claims a "cartridge assembly" in combination with a "dosing assembly." The "cartridge assembly" "includes a molded cartridge" with a stopper. Claim 26 further requires that the "cartridge assembly" includes two coupling means for engaging, respectively, a needle assembly and the dosing assembly. Finally, claim 26 recites that "at least one of said coupling means is unitarily molded with the **cartridge**" (in contrast, the other coupling means can be located either on any element of the **cartridge assembly**).

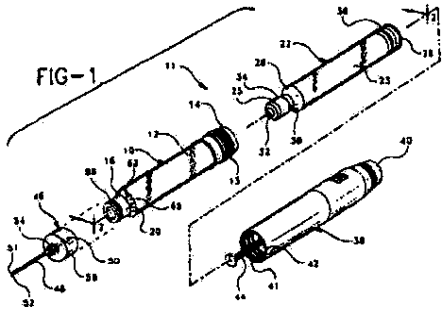
In the final rejection, the Examiner rejected claim 26 as being anticipated by Dibiasi et al. U.S. patent No. 6,146,361. The Examiner applied the elements disclosed in Dibiasi to claim 26 as follows:

Claim 26	Dibiasi
a molded cartridge	cartridge 22
first coupling means to engage a needle	threads 88 on the "cartridge retainer" 10
second coupling means to engage a dosing assembly	threads 13 on the cartridge retainer 10
one of the coupling means unitarily molded with the cartridge	threads 88 and 13 are both molded on the cartridge retainer 10; thus, DiBiasi fails to disclose any coupling means on the cartridge

Final Office Action, Paragraph 2.

The European counterpart of Dibiasi is discussed in the present specification on pages 1-2. As noted therein, the "cartridge assembly" of Dibiasi includes both a cartridge and a cartridge holder. And, while the "cartridge assembly" includes two coupling means, for a needle and for the dosing housing, respectively, both coupling means are provided on the cartridge holder. Neither of the coupling means are located on the cartridge itself, as specified in claim 26. This is evident from Figure 1 of Dibiasi, as shown below:

FIG-1



In the final rejection, the Examiner correctly stated that the element 22 corresponds to the "cartridge" recited in claim 26. And, insofar as the Examiner found the first and second coupling means of the "cartridge assembly" recited in claim 26 could be found on the cartridge holder 10 (threads 13 and 88 of Dibiasi), it is evident that the Examiner construed the term "cartridge assembly" in claim 26 to encompass two elements of Dibiasi: the cartridge holder 10 along with the cartridge 22 itself.

Thus, insofar as claim 26 recites that the "cartridge assembly" includes a first and second coupling means, the Examiner correctly found that the

"cartridge assembly" of Dibiasi includes two coupling means. However, claim 26 does not merely specify that the **cartridge assembly** include the two coupling means. Claim 26 specifies that "at least one of said coupling means is unitarily molded with the **cartridge**."

In the final rejection, the Examiner correctly found that neither of the coupling means (threads 13 and 88) of Dibiasi were provided on the **cartridge 22**. Rather, the Examiner found both coupling means (threads 13 and 88) to be on the other element of the "cartridge assembly," namely, the cartridge holder 10.

Thus, Dibiasi clearly does not disclose a syringe in which "at least one of said coupling means is unitarily molded with the cartridge." For such reason, the rejection of claim 26 as anticipated by Dibiasi is unsupportable, and the applicants respectfully request the Examiner to reconsider and withdraw such rejection (as well as the rejection of the dependent claims).

Also, in connection with dependent claim 6, the Examiner states that the invention would perform equally with a glass cartridge and that the use of plastic does not serve any particular purpose. However, plastic is a preferred material because it is easy to machine and the plastic can be molded more easily with smaller tolerances. Moreover, in the case of a glass cartridge, the cartridge holder performs the function of protecting the cartridge. Where a coupling means is provided directly on the cartridge, rather than on an a cartridge holder, torque or other forces are applied directly to the glass cartridge when another component is attached to or

removed from the cartridge, which could potentially cause a glass cartridge to break. For such additional reason, the applicants respectfully request favorable reconsideration of dependent claim 6.

For all the foregoing reasons, the applicants respectfully request reconsideration and allowance of the pending claims.

Respectfully submitted,

Robert B. Smith

Robert B. Smith
PTO Registration No. 28,538
Attorney for applicant(s)
(212) 735-3020

UNITED STA[illegible]3 DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/348,536	07/07/99	BUCH-RASMUSSEN T	5637.204-US

EXAMINER

QM32/0627

STEVE T ZELSON ESQ
NOVO NORDISK OF NORTH AMERICA INC
405 LEXINGTON AVENUE SUITE 6400
NEW YORK NY 10174-6401

SIMMONS,K

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 06/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/85)
*U.S. GPO: 2000-473-000/44602

1- File Copy

SAN00828310

Office Action Summary

Application No.	Applicant(s)
09/348,536	Thomas Bush-Rasmussen et al
Examiner	**Art Unit**
Kevin C. Simmons	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 13, 2001*

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *2-7, 10-12, and 26-28* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *2-7, 10-12, and 26-28* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s) _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> > (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

2. Claims 26-28, 2-4, 6, 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Chanoch U.S. Pat. No. 5,688,251.

Chanoch discloses a medication delivery device comprising: a cartridge assembly (300&350) having opposite ends, and a dosing assembly (100), wherein said cartridge assembly includes a molded cartridge (300&350) and a stopper disposed in said cartridge (306), wherein one end (distal end of 300&350) of said cartridge assembly is sealed with a pierceable sealing (353), wherein said one end includes a first coupling means (see fig. 4) for releasably mounting a needle assembly having a skin-piercing needle (501), and wherein the other end of said cartridge assembly includes a second coupling means (303) for engaging said dosing assembly (100), wherein at least one of said coupling means is unitarily molded with the cartridge (since 300&350 in combination are the cartridge, then, 303 represents the coupling means on the distal and proximal end of the cartridge), and wherein said dosing assembly includes a housing (101),

plunger (fig. 4), and a mechanism for setting a desired dose and for moving said plunger (fig. 2&3), relative to said housing in an axial direction for administering a set dose (functional language), (figs. 2&3), and wherein said dosing assembly housing includes a coupling member (fig. 2&3) for engaging said second coupling means of said cartridge assembly (figs. 2&3); for securing said housing against axial movement relative to said cartridge assembly (figs. 2&3) and such that said plunger engages said stopper for moving said stopper in response to plunger movement (figs. 2&3); wherein both said coupling means of said cartridge assembly are unitarily molded with the cartridge (figs. 3 and 2); wherein the said at least one coupling means of said cartridge assembly is an external coupling (fig. 4); wherein the said at least one coupling means of said cartridge assembly is a threaded coupling (figs. 2&3); the coupling of the cartridge assembly are opposed (figs. 3 and 2); wherein the said at least one coupling means is said second coupling means (figs. 3 and 2); wherein said second coupling means is a threaded coupling (figs. 3 and 2); a dosing assembly with a scale (col. 5, lines 1-10); wherein the cartridge is molded of a plastic material (fig.2 and 3).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chanoch U.S. Pat. No. 5,688,251.

Chanoch discloses a medication delivery device substantially as claimed except for: wherein the cartridge is at least partly transparent (figs. 3 and 2). However, Chanoch discloses that the cartridge is made of plastic. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the plastic cartridge of Chanoch since it well known that plastics can be made transparent.

Response to Arguments

5. Applicant's arguments with respect to claims 2-7, 10, 12, and 26-28 have been considered but are moot in view of the new ground(s) of rejection.

6. Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703)306-5410.

The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

KC.S

Kevin C. Sirmons

Patent Examiner

6/19/01

RICHARD K. SEIDEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

06/01/01

AF/3763

Docket No. 5637.200-US

#17

Notice of Appeal S. Byce 7/30/01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Buch-Rasmussen et al.

Serial No. : 09/348,536 Examiner: Simons, K.

Filed : July 7, 1999 Art Unit: 3763

Title : Medication Delivery Device

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on June 15, 2001.

Robert B. Smith Reg. No. 28,538

Robert B. Smith
Signature

June 15, 2001
Date

June 15, 2001

NOTICE OF APPEAL

BOX AF
Assistant Commissioner For Patents
Washington, DC 20231

Sir:

The applicant(s) hereby appeal(s) to the Board of Patent Appeals and Interferences from the decision dated January 17, 2001, of the Primary Examiner finally rejecting claims 2-7, 10, 12, and 26-28.

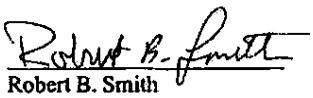
A two month extension of time has already been obtained.

Docket No. 5637.200-US

The Commissioner is hereby authorized to charge Deposit Account No. 19-2385 the sum of $310.00 representing (a) the appeal fee ($310).

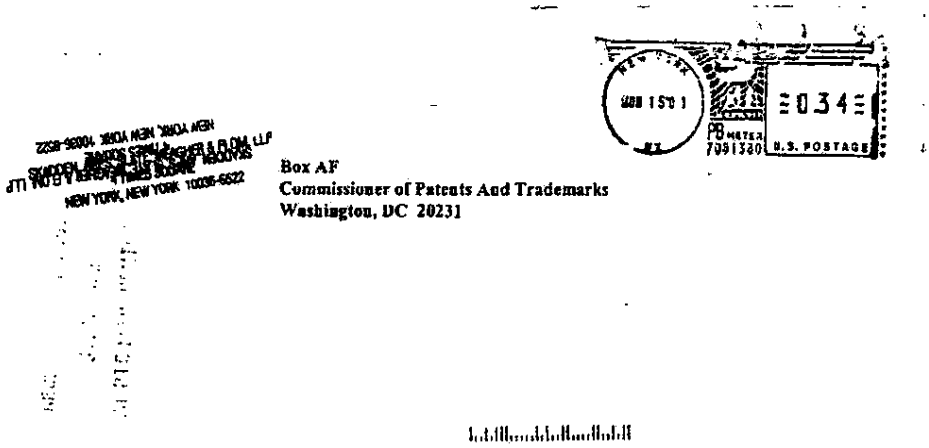
In the event that a further extension of time is needed, such extension is provisionally requested, and the Commissioner is authorized to charge payment of such extension fee, along with any additional fees required in connection with this communication, to Deposit Account No. 19-2385. A copy of this sheet is included for such purpose.

Respectfully submitted,



Robert B. Smith
PTO Registration No. 28,538
Attorney for applicant(s)

Skadden, Arps , Slate, Meagher, & Flom
Four Times Square
New York, NY 10036-6522
(212) 735-3020



SAN00828319

Docket No. 5637.200-US

#18
Rivers
1/17/02

SKADDEN, ARPS, SLATE, MEAGHER & FLOM
Four Times Square
New York, NY 10036-6522

Telephone: (212) 735-3020
Facsimile: (917) 777-3020

Date: October 25, 2001

Applicant(s)	:	Buch-Rasmussen et al.	
Serial No.	:	09/348,536	Examiner: Simons, K.
Filed	:	July 7, 1999	Art Unit: 3763
Title	:	Medication Delivery Device	

AMENDMENT TRANSMITTAL
AND REQUEST FOR EXTENSION OF TIME

Assistant Commissioner For Patents
Washington, DC 20231

Sir:

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on October 25, 2001.

Robert B. Smith — Reg. No. 28,538

Robert B. Smith — October 25, 2001
Signature — Date

Transmitted herewith is an AMENDMENT in the above-identified application.

1. ( ) No additional fee is required.

Docket No. 5637.200-US

2. ( ) The fee has been calculated as shown below:

Claims remaining	Prior Paid Claims	Extra	Rate	Fee
Total:	minus (at least 20) –	@	$18 =	$
Independent	minus (at least 3) –	@	$80 =	$___

TOTAL ADDITIONAL FEE: $

3. (X) An extension of time to respond to the PTO Communication dated June 27, 2001 is hereby requested. The required fee is indicated below:

Within first month:	(X)	$110
Within second month	( )	$390
Within third month	( )	$890
Within fourth month	( )	$1,390

4. ( ) The Amendment includes an Information Disclosure Statement. Enclosed is Form PTO-1449 and copies of ____ reference(s).

5. (X) The Commissioner is hereby authorized to charge the amount of $ 110.00 representing (a) additional claims fee ($); (b) the extension fee ($ 110); and (c) the fee for filing an Information Disclosure Statement ($) to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.

6. (X) In the event that an extension of time is required and applicant has inadvertently overlooked the need to request a petition and file the fee, the applicant hereby petitions for such extension of time. The Commissioner is authorized to charge the required fee to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.

7. (X) The Commissioner is hereby authorized to charge payment of any additional fees required in connection with this application, and credit any overpayment, to deposit account No. 19-2385. A copy of this sheet is enclosed.

Skadden, Arps, Slate, Meagher & Flom

By Robert B. Smith

Robert B. Smith
Registration No. 28,538
Attorneys for Applicant(s)
(212) 735-3020

COPY

Docket No. 5637.200-US

SKADDEN, ARPS, SLATE, MEAGHER & FLOM
Four Times Square
New York, NY 10036-6522

Telephone: (212) 735-3020
Facsimile: (917) 777-3020

Date: October 25, 2001

Applicant(s)	:	Buch-Rasmussen et al.	
Serial No.	:	09/348,536	Examiner: Simons, K.
Filed	:	July 7, 1999	Art Unit: 3763
Title	:	Medication Delivery Device	

AMENDMENT TRANSMITTAL
AND REQUEST FOR EXTENSION OF TIME

Assistant Commissioner For Patents
Washington, DC 20231

Sir:

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on October 25, 2001

Robert B. Smith — Reg. No. 28,538

Robert B Smith — October 25, 2001
Signature — Date

Transmitted herewith is an AMENDMENT in the above-identified application.

1. ( ) No additional fee is required.

01/23/2002 HMARZI1 00000032 .12385 09348536
01 FC:115 110.00 OH

2. ( ) The fee has been calculated as shown below:

Claims remaining	Prior Paid Claims	Extra	Rate	Fee
Total:	minus (at least 20) =	@	$18	= $
Independent	minus (at least 3) =	@	$80	= $___

TOTAL ADDITIONAL FEE: $

3. (X) An extension of time to respond to the PTO Communication dated June 27, 2001 is hereby requested. The required fee is indicated below:

Within first month:	(X)	$110
Within second month	( )	$390
Within third month	( )	$890
Within fourth month	( )	$1,390

4. ( ) The Amendment includes an Information Disclosure Statement. Enclosed is Form PTO-1449 and copies of ____ reference(s).

5. (X) The Commissioner is hereby authorized to charge the amount of $ 110.00 representing (a) additional claims fee ($); (b) the extension fee ($ 110); and (c) the fee for filing an Information Disclosure Statement ($) to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.

6. (X) In the event that an extension of time is required and applicant has inadvertently overlooked the need to request a petition and file the fee, the applicant hereby petitions for such extension of time. The Commissioner is authorized to charge the required fee to deposit account No. 19-2385. A copy of this sheet is enclosed for such purpose.

7. (X) The Commissioner is hereby authorized to charge payment of any additional fees required in connection with this application, and credit any overpayment, to deposit account No. 19-2385. A copy of this sheet is enclosed.

Skadden, Arps, Slate, Meagher & Flom

By Robert B. Smith

Robert B. Smith
Registration No. 28,538
Attorneys for Applicant(s)
(212) 735-3020

Docket No. 5637.200-US

#19
ARGUED
1/17/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Buch-Rasmussen et al.

Serial No. : 09/348,536 Examiner: Simons, K.

Filed : July 7, 1999 Art Unit: 3763

Title : Medication Delivery Device

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on October 25, 2001.

Robert B. Smith Reg. No. 28,538

Robert B. Smith
Signature

October 25, 2001
Date

October 25, 2001

RESPONSE TO OFFICE ACTION

Assistant Commissioner For Patents
Washington, DC 20231

Sir:

The applicants respectfully request reconsideration of the rejection of claims 2-7, 10-12, and 26-28, mailed on June 27, 2001. The applicants respectfully request, in particular, that the Examiner reconsider the assertion that the cartridge holder element 300 of the cited Chanoch patent can be deemed to be part of a

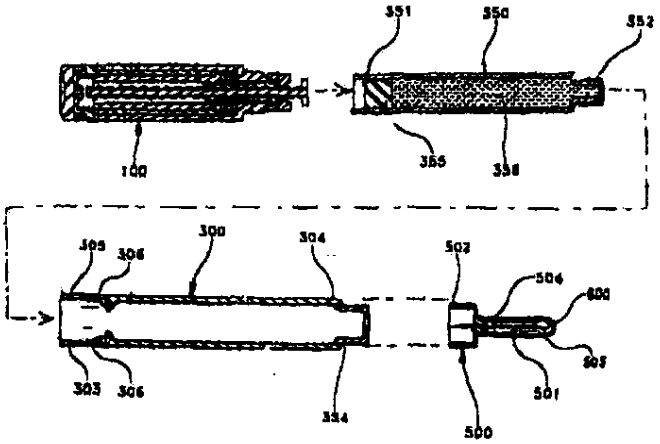
"molded cartridge" element as recited in claim 26. In requesting reconsideration, the applicants note that the Examiner's position that the cartridge holder 300 of Chanoch can be deemed to be part of a "molded cartridge" as recited in claim 26 is inconsistent with the Examiner's interpretation of DiBiasi U.S. patent No. 6,146,361, set forth in the final rejection dated January 17, 2001. In previously applying DiBiasi to claim 26, the Examiner asserted that the element in DiBiasi corresponding to the "molded cartridge" in claim 26 constitutes the cartridge 22 only, and not the cartridge holder.

Claim 26 claims a "cartridge assembly" that includes a "molded cartridge" with a stopper. Claim 26 further requires that the "cartridge assembly" includes two coupling means for engaging, respectively, a needle assembly and the dosing assembly. Finally, claim 26 recites that "at least one of said coupling means is unitarily molded with the cartridge" (i.e., at least one of the coupling means must be unitarily molded with the cartridge, and not merely associated with the cartridge assembly).

Chanoch U.S. patent No. 5,688,251 discloses a pen type syringe which includes a "cartridge holder assembly 300" that includes "a molded housing 304." Col. 5, lines 50-51. A "medication cartridge 350 [is] securely retained in housing 304." Col. 6, lines 1-2. More particularly, a "cap 354 extends between housing 304 and cartridge 350 for securely and permanently holding medication cartridge in housing 304." Col. 6, lines 3-8. Finally, a needle cannula assembly 500

has a mounting hub 504 which is "threadingly engageable with the cap 354." Col. 6, lines 15-20.

The disclosure that, but for the cap 354, the cartridge 350 can be separated from the cartridge holder housing 304 means that the housing 304 and cartridge 305 are separate elements, which are mechanically coupled to one another during some stage of the assembly process. Thus, if Fig. 2 of Chanoch were modified to show the parts of the syringe prior to such assembly, it would be as follows:



Thus, as evident from the Chanoch specification, the cartridge holder 300 is not molded unitarily with the cartridge 350 - they are separate elements.

As discussed above, claim 26 recites two coupling means for engaging, respectively, a needle assembly and the dosing assembly, and recites that "at

least one of said coupling means is unitarily molded with the [molded] cartridge." Chanoch discloses two coupling means: (1) internal threads 303 formed in the barrel of the cartridge holder 300 (which engage cooperating threads on the pen body 100), Col. 5, lines 55-57; and (2) threads on the external surface of the cap 354 (which engage internal threads provided in the needle hub 504). Col. 6, lines 18-20. Thus, Chanoch disclose two coupling means for engaging, respectively, a needle assembly and a dosing assembly. However, in Chanoch both such coupling means are provided on the cartridge holder, not on the "molded cartridge" itself. Thus, Chanoch does not anticipate or suggest claim 26.

The commonly owned Chanoch and DiBiasi patents both show a syringe having a cartridge holder element which screws onto a pen body. Both the cartridge holder of Chanoch and the cartridge holder of DiBiasi receive a separate cartridge. The difference between Chanoch and DiBiasi is that, in Chanoch, once the cartridge is inserted in the cartridge holder barrel, it cannot be removed. Thus, when the cartridge is empty, the user must replace both the cartridge and the cartridge holder. In contrast, DiBiasi allows the cartridge to be removed from the cartridge holder when empty, so that only the cartridge, and not the cartridge holder needs to be replaced. This difference is immaterial relative to the claims of the present application.

As discussed in the applicants's Response After Final Rejection dated June 11, 2001, in applying DiBiasi to claim 26, the Examiner did not consider the

cartridge holder to be part of the claimed "molded cartridge." Rather, the Examiner deemed the cartridge 22 of DiBiasi to correspond to the "molded cartridge" of claim 26, and treated the "cartridge retainer" 10 of DiBiasi to constitute a separate element. Final Office Action, Paragraph 2.

The cartridge holder and cartridge shown in DiBiasi are very similar to the cartridge holder and cartridge shown in Chanoch, except that, in Chanoch, the cartridge is permanently retained in the cartridge holder (and insofar as the cartridge holder barrel in Chanoch has internal threads to engage the pen body). Thus, it is inconsistent for the Examiner to deem the cartridge (but not the cartridge holder) to constitute a "molded cartridge" when interpreting DiBiasi, and yet to deem both the cartridge and the cartridge holder to constitute a "molded cartridge" when interpreting Chanoch.

For such reason, the applicants do not believe that the combination of the cartridge 350 and the cartridge holder 300 of Chanoch can properly be deemed to correspond to a "molded cartridge." Certainly, a person skilled in the art would not deem a cartridge holder to be part of a molded cartridge, as evidenced by the fact that the Chanoch specification clearly differentiates between a cartridge and a cartridge holder. *See, Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1578, 38 U.S.P.Q.2d 1126, 1129 (Fed. Cir. 1996) (stating that a claim term is to be given the meaning that it would be given by persons experienced in the field of invention).

Because the rejection of the claims hinges on the assertion that the cartridge holder 300 of Chanoch is part of a "molded cartridge," the applicants respectfully request reconsideration and allowance of the pending claims.

Respectfully submitted,

Robert B. Smith
PTO Registration No. 28,538
Attorney for applicant(s)
(212) 735-3020

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP

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FACSIMILE TRANSMITTAL SHEET

PLEASE DELIVER THE FOLLOWING PAGE(S) TO:

NAME:	Examiner Kevin C. Simpons		
FIRM:	USPTO		
CITY:	Arlington, VA	DATE:	January 14, 2002
TELEPHONE NO.:	(703) 306-5410		
FACSIMILE NO.:	(703) 306-4520		
FROM:	Robert B. Smith	FLR/RM.:	30-328
REFERENCE NO.:	021950	DIRECT DIAL:	(212) 735-3020
TOTAL NUMBER OF PAGES INCLUDING COVER(S):			9

MESSAGE:

Copy #17

Docket No. 5637.200-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	Buch-Rasmussen et al.	
Serial No.	:	09/348,536	Examiner: Simons, K.
Filed	:	July 7, 1999	Art Unit: 3763
Title	:	Medication Delivery Device	

I hereby certify that this paper is being deposited with the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on October 25, 2001.

Robert B. Smith — Reg. No. 28,538

Robert B. Smith — Signature

October 25, 2001 — Date

October 25, 2001

RESPONSE TO OFFICE ACTION

Assistant Commissioner For Patents
Washington, DC 20231

Sir:

The applicants respectfully request reconsideration of the rejection of claims 2-7, 10-12, and 26-28, mailed on June 27, 2001. The applicants respectfully request, in particular, that the Examiner reconsider the assertion that the cartridge holder element 300 of the cited Chanoch patent can be deemed to be part of a

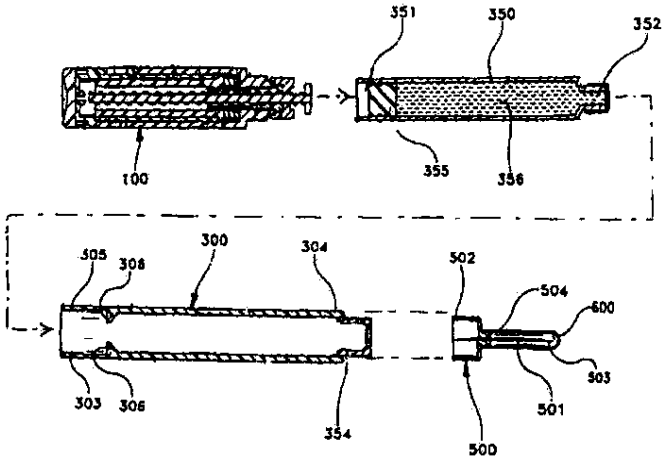
"molded cartridge" element as recited in claim 26. In requesting reconsideration, the applicants note that the Examiner's position that the cartridge holder 300 of Chanoch can be deemed to be part of a "molded cartridge" as recited in claim 26 is inconsistent with the Examiner's interpretation of DiBiasi U.S. patent No. 6,146,361, set forth in the final rejection dated January 17, 2001. In previously applying DiBiasi to claim 26, the Examiner asserted that the element in DiBiasi corresponding to the "molded cartridge" in claim 26 constitutes the cartridge 22 only, and not the cartridge holder.

Claim 26 claims a "cartridge assembly" that includes a "molded cartridge" with a stopper. Claim 26 further requires that the "cartridge assembly" includes two coupling means for engaging, respectively, a needle assembly and the dosing assembly. Finally, claim 26 recites that "at least one of said coupling means is unitarily molded with the cartridge" (i.e., at least one of the coupling means must be unitarily molded with the cartridge, and not merely associated with the cartridge assembly).

Chanoch U.S. patent No. 5,688,251 discloses a pen type syringe which includes a "cartridge holder assembly 300" that includes "a molded housing 304." Col. 5, lines 50-51. A "medication cartridge 350 [is] securely retained in housing 304." Col. 6, lines 1-2. More particularly, a "cap 354 extends between housing 304 and cartridge 350 for securely and permanently holding medication cartridge in housing 304." Col. 6, lines 3-8. Finally, a needle cannula assembly 500

has a mounting hub 504 which is "threadingly engageable with the cap 354." Col. 6, lines 15-20.

The disclosure that, but for the cap 354, the cartridge 350 can be separated from the cartridge holder housing 304 means that the housing 304 and cartridge 305 are separate elements, which are mechanically coupled to one another during some stage of the assembly process. Thus, if Fig. 2 of Chanoch were modified to show the parts of the syringe prior to such assembly, it would be as follows:



Thus, as evident from the Chanoch specification, the cartridge holder 300 is not molded unitarily with the cartridge 350 - they are separate elements.

As discussed above, claim 26 recites two coupling means for engaging, respectively, a needle assembly and the dosing assembly, and recites that "at

least one of said coupling means is unitarily molded with the [molded] cartridge." Chanoch discloses two coupling means: (1) internal threads 303 formed in the barrel of the cartridge holder 300 (which engage cooperating threads on the pen body 100), Col. 5, lines 55-57; and (2) threads on the external surface of the cap 354 (which engage internal threads provided in the needle hub 504). Col. 6, lines 18-20. Thus, Chanoch disclose two coupling means for engaging, respectively, a needle assembly and a dosing assembly. However, in Chanoch both such coupling means are provided on the cartridge holder, not on the "molded cartridge" itself. Thus, Chanoch does not anticipate or suggest claim 26.

The commonly owned Chanoch and DiBiasi patents both show a syringe having a cartridge holder element which screws onto a pen body. Both the cartridge holder of Chanoch and the cartridge holder of DiBiasi receive a separate cartridge. The difference between Chanoch and DiBiasi is that, in Chanoch, once the cartridge is inserted in the cartridge holder barrel, it cannot be removed. Thus, when the cartridge is empty, the user must replace both the cartridge and the cartridge holder. In contrast, DiBiasi allows the cartridge to be removed from the cartridge holder when empty, so that only the cartridge, and not the cartridge holder needs to be replaced. This difference is immaterial relative to the claims of the present application.

As discussed in the applicants's Response After Final Rejection dated June 11, 2001, in applying DiBiasi to claim 26, the Examiner did not consider the

cartridge holder to be part of the claimed "molded cartridge." Rather, the Examiner deemed the cartridge 22 of DiBiasi to correspond to the "molded cartridge" of claim 26, and treated the "cartridge retainer" 10 of DiBiasi to constitute a separate element. Final Office Action, Paragraph 2.

The cartridge holder and cartridge shown in DiBiasi are very similar to the cartridge holder and cartridge shown in Chanoch, except that, in Chanoch, the cartridge is permanently retained in the cartridge holder (and insofar as the cartridge holder barrel in Chanoch has internal threads to engage the pen body). Thus, it is inconsistent for the Examiner to deem the cartridge (but not the cartridge holder) to constitute a "molded cartridge" when interpreting DiBiasi, and yet to deem both the cartridge and the cartridge holder to constitute a "molded cartridge" when interpreting Chanoch.

For such reason, the applicants do not believe that the combination of the cartridge 350 and the cartridge holder 300 of Chanoch can properly be deemed to correspond to a "molded cartridge." Certainly, a person skilled in the art would not deem a cartridge holder to be part of a molded cartridge, as evidenced by the fact that the Chanoch specification clearly differentiates between a cartridge and a cartridge holder. *See, Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1578, 38 U.S.P.Q.2d 1126, 1129 (Fed. Cir. 1996) (stating that a claim term is to be given the meaning that it would be given by persons experienced in the field of invention).

Because the rejection of the claims hinges on the assertion that the cartridge holder 300 of Chanoch is part of a "molded cartridge," the applicants respectfully request reconsideration and allowance of the pending claims.

Respectfully submitted,

Robert B. Smith
PTO Registration No. 28,538
Attorney for applicant(s)
(212) 735-3020

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/348,536	07/07/1999	THOMAS BUCH-RASMUSSEN	5637.200-US	5366

26137 7590 04/30/2002

PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK, NY 10036

EXAMINER	
SIRMONS, KEVIN C	

ART UNIT	PAPER NUMBER
3783	

DATE MAILED: 04/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No.	Applicant(s)	
	09/348,536	BUCH-RASMUSSEN ET AL.	
	Examiner	Art Unit	
	Kevin C. Simons	3783	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-7,10-12 and 26-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6, 7, 10-12 and 26-28* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

U.S. Patent and Trademark Office
PTO-326 (Rev. 04-01) Office Action Summary Part of Paper No. 20

DETAILED ACTION

Claim Rejections - 35 USC § 102

I. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

II. Claims 26-28, 2-4, 6, 10 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Chanoch U.S. Pat. No. 5,688,251.

Chanoch discloses a medication delivery device comprising: a cartridge assembly (300&350) having opposite ends, and a dosing assembly (100), wherein said cartridge assembly includes a molded cartridge (300&350) and a stopper disposed in said cartridge (306), wherein one end (distal end of 300&350) of said cartridge assembly is sealed with a pierceable sealing (353), wherein said one end includes a first coupling means (see fig. 4) for releasably mounting a needle assembly having a skin-piercing needle (501), and wherein the other end of said cartridge assembly includes a second coupling means (303) for engaging said dosing assembly (100), wherein at least one of said coupling means is unitarily molded with the cartridge (since 300&350 in combination are the cartridge, then, 303 represents the coupling means on the distal and proximal end of the cartridge), and wherein said dosing assembly includes a housing (101), plunger (fig. 4), and a mechanism for setting a desired dose and for moving said plunger (fig. 2&3), relative to said housing in an axial direction for administering a set dose (functional language), (figs. 2&3),

and wherein said dosing assembly housing includes a coupling member (fig. 2&3) for engaging said second coupling means of said cartridge assembly (figs. 2&3); for securing said housing against axial movement relative to said cartridge assembly (figs. 2&3) and such that said plunger engages said stopper for moving said stopper in response to plunger movement (figs. 2&3); wherein both said coupling means of said cartridge assembly are unitarily molded with the cartridge (figs. 3 and 2); wherein the said at least one coupling means of said cartridge assembly is an external coupling (fig. 4); wherein the said at least one coupling means of said cartridge assembly is a threaded coupling (figs. 2&3); the coupling of the cartridge assembly are opposed (figs. 3 and 2); wherein the said at least one coupling means is said second coupling means (figs. 3 and 2); wherein said second coupling means is a threaded coupling (figs. 3 and 2); a dosing assembly with a scale (col. 5, lines 1-10); wherein the cartridge is molded of a plastic material (fig.2 and 3).

Claim Rejections - 35 USC § 103

III. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

IV. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chanoch U.S. Pat. No. 5,688,251.

Chanoch discloses a medication delivery device substantially as claimed except for: wherein the cartridge is at least partly transparent (figs. 3 and 2). However, Chanoch discloses that the cartridge is made of plastic. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the plastic cartridge of Chanoch since it well known that plastics can be made transparent.

Response to Arguments

Applicant's arguments filed 1/14/02 have been fully considered but they are not persuasive.

Note: the examiner will address argument only directed to the current art rejection.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "at least one of said coupling means is unitarily molded with the **cartridge**") (i.e., at least one if the coupling means must be unitarily molded with the cartridge, and not merely associated with the cartridge assembly). Simply, applicant discloses a cartridge assembly (1) and a cartridge (5) which both characters "1" and "5" have been used to designate one specific part clearly shown in (fig. 3). Chanoch clearly discloses a cartridge assembly (300 & 350) and a cartridge (300 & 350) which have been used to designate one specific part shown in (figs. 2-4). The cartridge assembly and cartridge are secured together. Evidently they are not separable! Basically, they are considered to be a whole, one unit.

V. Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

KCS

Kevin C. Sirmons

Patent Examiner
4/25/02

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

AF/3

Attorney Docket No.: 5637.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/348,536

Group Art Unit: 3763

Filed: July 30, 2002

Examiner: To be assigned

Confirmation No: 5366

Please Enter KCS 9/17/02

For: Medication Delivery Device

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Amendment and Response After Final Rejection

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner for Patents
Washington, DC 20231

on July 30, 2002.

Maya Faison-Phillip
(name of person mailing paper)

(signature of person mailing paper)

Attorney Docket No.: 5637.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Application No.: 09/348,536

Filed: July 30, 2002

Confirmation No: 5366

Group Art Unit: 3763

Examiner: To be assigned

For: Medication Delivery Device

AMENDMENT AND RESPONSE AFTER FINAL REJECTION

Commissioner for Patents
Washington, DC 20231

Sir:

In response to the Office Action mailed 4/30/02, applicants respectfully request entry of the following amendment and remarks, and reconsideration of the final rejection of the pending claims. Accordingly, please amend the above-captioned application as follows:

IN THE CLAIMS:

Please cancel claim 5 without prejudice or disclaimer.

Please add new claim 29:

29. (New) A medication delivery device comprising a cartridge assembly having opposite ends and a dosing assembly for setting a desired dose and acting on the cartridge assembly to cause the desired dose to be delivered, wherein:

the cartridge assembly includes a molded cartridge and a stopper disposed in the cartridge, wherein one end of the cartridge assembly is sealed with a pierceable sealing, wherein the one end includes a first coupling means for releasably mounting a needle assembly having a skin-piercing needle, and wherein the other end of the cartridge assembly includes a second coupling means for engaging the dosing assembly, wherein at least one of the coupling means is unitarily molded with the cartridge, and wherein the dosing assembly includes a housing, a plunger, and a mechanism for setting a desired dose and for moving the plunger relative to the housing in an axial direction for administering a set dose, and wherein the dosing assembly housing includes a coupling member for engaging the second coupling means of the cartridge assembly for securing the housing against axial movement relative to the cartridge assembly such that the plunger engages the stopper for moving the stopper in response to the plunger movement wherein the at least one coupling means of the cartridge assembly is a threaded coupling and wherein the second coupling means is an external threaded coupling.

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REMARKS

Claim 5 has been canceled without prejudice or disclaimer. New claim 29 is an independent version of cancelled claim 5 and includes all the limitation of the base claim and any intervening claims upon which claim 5 depended.

It is respectfully submitted that the present amendment presents no new issues or new matter and places claim 29 in condition for allowance, thus reducing issues on appeal, should an appeal become necessary.

In the previous office action, the Examiner finally rejected all pending claims, except for claim 5, under 35 USC 102(e) in view of U.S. Patent No. 5,699,251 to Chanoch. Applicants respectfully request reconsideration in view of the following remarks.

Applicants respectfully disagree with the Examiners assertion in the previous office action that the Chanoch device operates with a cartridge assembly in a similar manner to the applicants invention as defined by the pending claims. While Chanoch might be viewed as showing a cartridge holder assembly comprising a cartridge and coupling means for mounting a dose setting part and for mounting an injection needle, applicants' invention as defined by the claims requires explicitly that at least one of the coupling means is unitarily molded with the cartridge. This feature is not found in Chanoch.

At best, Chanoch discloses that the cartridge holder assembly 300 is a unit comprising parts such as a housing 304, a cartridge 350, and coupling means 305 for coupling a pen body assembly to the cartridge holder assembly 300 and coupling means 303 for coupling an injection needle to the cartridge holder assembly. However, none of these coupling means 305 or 303 are unitarily molded with the cartridge 350 but are merely provided on the housing 304.

In the embodiment shown in figure 3 in the instant application the cartridge 5 is provided with both the mentioned coupling means 2 and 3 for coupling to the needle and to the pen body assembly, respectively. In this embodiment the cartridge 5 with its couplings 2 and 3 forms a cartridge assembly 1. This cartridge assembly 1 is molded as one integral part. In contrast Chanoch discloses that the cartridge holder assembly 300 comprises the cartridge 350 but the coupling means 305 and 303 are unitary molded with the housing 304, not with the cartridge 350.

Applicants respectfully disagree with any assertion that tries to equate the cartridge assembly 300 with the cartridge 350. Reference numeral 300 in Chanoch designates a collection of single elements of which the cartridge 350 is one. In contrast, applicants' figure 3 shows clearly that the cartridge 5 is one integral part which is provided with coupling means 2 and 3 to appear as a cartridge assembly 1. If only one of the coupling means had been provided for in applicants' molded cartridge, applicants cartridge assembly could have been constructed like the one shown by Chanoch with a cartridge holder assembly comprising a housing accommodating a cartridge and carrying the coupling means which were not provided on the cartridge, but even with this construction the device according to applicants' invention as claimed would differ from the Chanoch construction because at least one of the coupling means is unitarily molded with the cartridge.

As evidence that the reference numbers 1 and 300 designate assemblies and not single parts applicants point out that Chanoch's reference lines are provided with an arrow widely pointing at the assembly referred to. Elsewhere, Chanoch used other reference lines that each lead to a single part or feature.

In sum, applicants respectfully note that Chanoch's cartridge holder assembly 300 only superficially appears like applicants' cartridge assembly as claimed but, upon a detailed review, the construction of the two assemblies differs.

Channoch's assembly is built from at least two parts: a housing carrying coupling means and a common cartridge. In contrast, applicants' invention as defined by the claims requires that in the assembly the cartridge is special as it carries at least one of the coupling means. A housing may be provided carrying the other coupling means, or the assembly may be made as one integral part as the one shown in figure 3, but still at least one coupling means is unitarily molded with the cartridge.

CONCLUSION

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Applicants respectfully request withdrawal of the final rejection and reconsideration and allowance of the pending claims. The Examiner is hereby invited to contact the attorney for the applicants by telephone if there are any questions concerning this amendment or application. Should any fee be due in connection with this paper or this application, the Commissioner is hereby authorized to charge any fee to Deposit Account No. 14-1447.

Respectfully submitted,

Date: July 30, 2002

Marc A. Began, Reg. No. 48,829
Novo Nordisk of North America, Inc.
405 Lexington Avenue, Suite 6400
New York, NY 10174-6401
(212) 867-0123

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Notice of Allowability	Application No. 09/348,536	Applicant(s) BUCH-RASMUSSEN ET AL.	
	Examiner Kevin C. Simmons	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *8/20/01*.
2. ☒ The allowed claim(s) is/are *2,3,6,7,10,11 and 29*.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☒ Certified copies of the priority documents have been received. Certified Copy @ PTO.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____.
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
   (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

8. ☒ CORRECTED DRAWINGS must be submitted.
   (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☒ to Paper No. *8*.
   (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
   (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1☐ Notice of References Cited (PTO-892)
2☐ Notice of Informal Patent Application (PTO-152)
3☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
4☐ Interview Summary (PTO-413), Paper No. _____.
5☐ Information Disclosure Statements (PTO-1449), Paper No. _____.
6☒ Examiner's Amendment/Comment
7☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
8☐ Examiner's Statement of Reasons for Allowance
9☐ Other

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Marc A. Began on 9/10/02.

The application has been amended as follows:

Please cancel claims 4 and 26-28.

In claim 2, at line 2 after "claim"

"26" has been deleted,

--29--has been inserted.

In claim 3, at line 2 after "claim"

"26" has been deleted,

--29--has been inserted.

In claim 6, at line 2 after "claim"

"26" has been deleted,

--29--has been inserted.

In claim 10, at line 2 after "claim"

"26" has been deleted,

--29--has been inserted.

In claim 12, at line 2 after "claim"

"26" has been deleted,

--29--has been inserted.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Sirmons whose telephone number is 703-306-5410. The examiner can normally be reached on Monday-Friday 6:30-4:00 ALT FRI.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-306-4520 for regular communications and 703-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0000.

KCS

Kevin C. Sirmons
Patent Examiner
September 17, 2002

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Washington, D.C. 20231
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

26137 7590 09/20/2002

PATENT DEPARTMENT
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FOUR TIMES SQUARE
NEW YORK, NY 10036

EXAMINER	
SIRMONS, KEVIN C	
ART UNIT	**CLASS-SUBCLASS**
3763	604-232000

DATE MAILED: 09/20/2002

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/348,536	07/07/1999	THOMAS BUCH-RASMUSSEN	5637.200-US	5366

TITLE OF INVENTION: MEDICATION DELIVERY DEVICE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1280	$0	$1280	12/20/2002

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☐ Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (REV. 04-02) Approved for use through 01/31/2004.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Box ISSUE FEE
Commissioner for Patents
Washington, D.C. 20231
Fax (703)746-4000

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

26137 7590 09/20/2002

PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK, NY 10036

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above, or being facsimile transmitted to the USPTO, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/348,536	07/07/1999	THOMAS BUCH-RASMUSSEN	5637.200-US	5366

TITLE OF INVENTION: MEDICATION DELIVERY DEVICE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1280	$0	$1280	12/20/2002

EXAMINER	ART UNIT	CLASS-SUBCLASS
SIMMONS, KEVIN C	3763	604-232000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) ☐ individual ☐ corporation or other private group entity ☐ government

4a. The following fee(s) are enclosed:

☐ Issue Fee
☐ Publication Fee
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s):

☐ A check in the amount of the fee(s) is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature) (Date)

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMIT THIS FORM WITH FEE(S)

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/348,536	07/07/1999	THOMAS BUCH-RASMUSSEN	5637.200-US	5366

26137 7590 09/20/2002

PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK, NY 10036
UNITED STATES

EXAMINER	
SIRMONS, KEVIN C	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 09/20/2002

Determination of Patent Term Extension under 35 U.S.C. 154 (b)
(application filed after June 7, 1995 but prior to May 29, 2000)

The patent term extension is 0 days. Any patent to issue from the above identified application will include an indication of the 0 day extension on the front page.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (http://pair.uspto.gov)

PTOL-85 (REV. 04-02) Approved for use through 03/31/2004.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/348,536	07/07/1999	THOMAS BUCH-RASMUSSEN	5637.200-US	5366

26137 7590 09/20/2002

PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK, NY 10036
UNITED STATES

EXAMINER	
SIRMONS, KEVIN C	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 09/20/2002

Notice of Possible Fee Increase on October 1, 2002

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after October 1, 2002, then the amount due may be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there may be an increase in fees effective on October 1, 2002. See Revision of Patent and Trademark Fees for Fiscal Year 2003: Notice of Proposed Rulemaking, 67 Fed. Reg. 30634, 30636 (May 7, 2002). Although a change to the amount of the publication fee is not currently proposed for October 2002, if the issue fee or publication fee is to be paid on or after October 1, 2002, applicant should check the USPTO web site for the current fees before submitting the payment. The USPTO Internet address for the fee schedule is: http://www.uspto.gov/main/howtofees.htm.

If the issue fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due," but not the correct amount in view of any fee increase, a "Notice to Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice to Pay Balance of Issue Fee," if the response to the Notice of Allowance and Fee(s) due form is to be filed on or after October 1, 2002 (or mailed with a certificate of mailing on or after October 1, 2002), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

Form PTO-948 (Rev. 8-98) U.S. DEPARTMENT OF COMMERCE - Patent and Trademark Office Application No. 348536

NOTICE OF DRAFTSPERSON'S PATENT DRAWING REVIEW

The drawing(s) filed (insert date) 7/7/99 are:

A. ☐ approved by the Draftsperson under 37 CFR 1.84 or 1.152.

B. ☒ objected to by the Draftsperson under 37 CFR 1.84 or 1.152 for the reasons indicated below. The Examiner will require submission of new, corrected drawings when necessary. Corrected drawing must be sumitted according to the instructions on the back of this notice.

1. DRAWINGS. 37 CFR 1.84(a): Acceptable categories of drawings: Black ink. Color.
   - ___ Color drawings are not acceptable until petition is granted. Fig(s) ___
   - ___ Pencil and non black ink not permitted. Fig(s) ___
2. PHOTOGRAPHS. 37 CFR 1.84 (b)
   - ___ 1 full-tone set is required. Fig(s) ___
   - ___ Photographs not properly mounted (must use bristol board or photographic double-weight paper). Fig(s) ___
   - ___ Poor quality (half-tone). Fig(s) ___
3. TYPE OF PAPER. 37 CFR 1.84(e)
   - ___ Paper not flexible, strong, white, and durable. Fig(s) ___
   - ___ Erasures, alterations, overwritings, interlineations, folds, copy machine marks not accepted. Fig(s) ___
   - ___ Mylar, velum paper is not acceptable (too thin). Fig(s) ___
4. SIZE OF PAPER. 37 CFR 1.84(f): Acceptable sizes:
   - ___ 21.0 cm by 29.7 cm (DIN size A4)
   - ___ 21.6 cm by 27.9 cm (8 1/2 x 11 inches)
   - ___ All drawing sheets not the same size. Sheet(s) ___
   - ___ Drawings sheets not an acceptable size. Fig(s) ___
5. MARGINS. 37 CFR 1.84(g): Acceptable margins:

   Top 2.5 cm Left 2.5cm Right 1.5 cm Bottom 1.0 cm SIZE: A4 Size

   Top 2.5 cm Left 2.5 cm Right 1.5 cm Bottom 1.0 cm SIZE: 8 1/2 x 11

   Margins not acceptable. Fig(s) ___
   - ___ Top (T) ___ Left (L)
   - ___ Right (R) ___ Bottom (B)
6. VIEWS. 37 CFR 1.84(h)

   REMINDER: Specification may require revision to correspond to drawing changes.

   Partial views. 37 CFR 1.84(h)(2)
   - ___ Brackets needed to show figure as one entity. Fig(s) ___
   - ___ Views not labeled separately or properly. Fig(s) ___
   - ___ Enlarged view not labeled separately or properly. Fig(s) ___
7. SECTIONAL VIEWS. 37 CFR 1.84 (h)(3)
   - ___ Hatching not indicated for sectional portions of an object. Fig(s) ___
   - ___ Sectional designation should be noted with Arabic or Roman numbers. Fig(s) ___
8. ARRANGEMENT OF VIEWS. 37 CFR 1.84(i)
   - ___ Words do not appear on a horizontal, left-to-right fashion when page is either upright or turned so that the top becomes the right side, except for graphs. Fig(s) ___
9. SCALE. 37 CFR 1.84(k)
   - ___ Scale not large enough to show mechanism without crowding when drawing is reduced in size to two-thirds in reproduction. Fig(s) ___
10. CHARACTER OF LINES, NUMBERS, & LETTERS. 37 CFR 1.84(l)
    - X Lines, numbers & letters not uniformly thick and well defined, clean, durable, and black (poor line quality). Fig(s) 2A-2B
11. SHADING. 37 CFR 1.84(m)
    - ___ Solid black areas pale. Fig(s) ___
    - ___ Solid black shading not permitted. Fig(s) ___
    - ___ Shade lines, pale, rough and blurred. Fig(s) ___
12. NUMBERS, LETTERS, & REFERENCE CHARACTERS. 37 CFR 1.84(p)
    - ___ Numbers and reference characters not plain and legible. Fig(s) ___
    - ___ Figure legends are poor. Fig(s) ___
    - ___ Numbers and reference characters not oriented in the same direction as the view. 37 CFR 1.84(p)(1) Fig(s) ___
    - ___ English alphabet not used. 37 CFR 1.84(p)(2) Figs ___
    - ___ Numbers, letters and reference characters must be at least .32 cm (1/8 inch) in height. 37 CFR 1.84(p)(3) Fig(s) ___
13. LEAD LINES. 37 CFR 1.84(q)
    - ___ Lead lines cross each other. Fig(s) ___
    - ___ Lead lines missing. Fig(s) ___
14. NUMBERING OF SHEETS OF DRAWINGS. 37 CFR 1.84(t)
    - ___ Sheets not numbered consecutively, and in Arabic numerals beginning with number 1. Sheet(s) ___
15. NUMBERING OF VIEWS. 37 CFR 1.84(u)
    - ___ Views not numbered consecutively, and in Arabic numerals, beginning with number 1. Fig(s) ___
16. CORRECTIONS. 37 CFR 1.84(w)
    - ___ Corrections not made from prior PTO-948 dated ___
17. DESIGN DRAWINGS. 37 CFR 1.152
    - ___ Surface shading shown not appropriate. Fig(s) ___
    - ___ Solid black shading not used for color contrast. Fig(s) ___

COMMENTS

REVIEWER S. Zielke DATE 12/23/99 TELEPHONE NO. 703 305-8535

ATTACHMENT TO PAPER NO. ___

PA-IDC #23

QUERY CONTROL FORM				RTIS USE ONLY	
Application No.	09348536	Prepared by	CWC	Tracking Number	05659482
Examiner-GAU	Casler 3763	Date	10-22-02	Week Date	9-30-02
		No. of queries	-1-		

JACKET			
a. Serial No.	f. Foreign Priority	k. Print Claim(s)	p. PTO-1449
b. Applicant(s)	g. Disclaimer	l. Print Fig.	q. PTOL-85b
c. Continuing Data	h. Microfiche Appendix	m. Searched Column	r. Abstract
d. PCT	i. Title	n. PTO-270/328	s. Sheets/Figs
e. Domestic Priority	j. Claims Allowed	o. PTO-892	t. Other

SPECIFICATION	MESSAGE
a. Page Missing	PTO-37 (#22) states that all certified copies have been received but none found in file.
b. Text Continuity	
c. Holes through Data	
d. Other Missing Text	
e. Illegible Text	Please advise
f. Duplicate Text	Thank you
g. Brief Description	CWC
h. Sequence Listing	
i. Appendix	
j. Amendments	
k. Other	
CLAIMS	
a. Claim(s) Missing	
b. Improper Dependency	
c. Duplicate Numbers	
d. Incorrect Numbering	initials
e. Index Disagrees	RESPONSE SEE PAPER 24
f. Punctuation	
g. Amendments	
h. Bracketing	
i. Missing Text	
j. Duplicate Text	
k. Other	initials

E-5 (Rev. 10/01/02)

FEB.11.2003 1:05PM NNNA LEGAL DEPT. NO.405 P.1/9

02-12-03
Paper # 25

novo nordisk®

NOVO NORDISK PHARMACEUTICALS, INC.

FACSIMILE TRANSMITTAL SHEET

TO: Examiner Ollie Person	FROM: Marc A. Began Esq.
COMPANY: United States Patent and Trademark Office	DATE: FEBRUARY 11, 2003
FAX NUMBER: 1 703-308-6642	TOTAL NO. OF PAGES INCLUDING COVER: 9
PHONE NUMBER:	SENDER'S PHONE NUMBER: 609-919-7829
RE: USSN: 09/348,536 Top Sheets of Foreign Priority Document PA 1998 00909 & PA 1998 01500	SENDER'S FAX NUMBER: 609-919-7741

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

Dear Ms. Person:

As requested, attached herewith are the top sheets of Foreign Priority Documents PA 1998 00909 and PA 1998 01500.

Applicants have previously submitted both the Foreign Priority Documents together with a Response to File Corrected Application Papers on December 10, 2002, and have received a date stamped return postcard from the USPTO that these documents were received by the USPTO on December 17, 2002. (copies enclosed)

Best Regards,

Marc A. Began, Reg. No. 48,829

Attorney Docket No. 5637.200-US

Patent Application entitled: "Medication Delivery Device"

Applicants: Buch-Rasmussen et al.

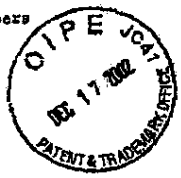
USSN: 09/348.536

The USPTO hereby acknowledges receipt of the following:
1. Certificate of Mailing
2. Response to Notice to File Corrected Application Papers (in duplicate)
3. Copy of Notice to File Corrected Application Papers
5. Certified Copies of Priority Application(s) (2)

NCBG/RHAJ

December 10, 2002

VIA First Class Mail



Attorney Docket No.: 5637.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/348,536 Group Art Unit: 3763

Filed: July 7, 1999 Examiner: Simmons, Kevin C

Confirmation No: 5366

For: Medication Delivery Device

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

1. Response to Notice to File Corrected Application Papers (in duplicate)
3. Copy of Notice to File Corrected Application Papers
4. Certified copies of Priority Application(s) (2)

is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner for Patents
Washington, DC 20231

on December 10, 2002.

Rashida Haji
(name of person mailing paper)

Rashida Haji
(signature of person mailing paper)

Attorney Docket No.: 5637.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/348,536 Group Art Unit:

Filed: July 7, 1999 Examiner: To be assigned

Confirmation No: 5366

For: Medication Delivery Device

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Commissioner for Patents
Washington, DC 20231

Sir:

In response to the Notice to File Corrected Application Papers dated November 13, 2002, (a copy thereof is attached hereto), Applicants enclose certified copy of Danish application nos. PA 1998 00909, filed July 8, 1998 and PA 1998 01500, filed November 17, 1998, priority of which is claimed under 35 U.S.C. 119.

Please charge any required fee, with this paper and credit any overpayments to Novo Nordisk Pharmaceuticals, Inc., Deposit Account No. 14-1447. Please charge any additional fees, should they be required, to Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,

Date: December 10, 2002

Marc A. Began, Reg. No. 48,829
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5800

Attorney Docket No.: 5637.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/348,536 Group Art Unit:

Filed: July 7, 1999 Examiner: To be assigned

Confirmation No: 5366

For: Medication Delivery Device

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Commissioner for Patents
Washington, DC 20231

Sir:

In response to the Notice to File Corrected Application Papers dated November 13, 2002, (a copy thereof is attached hereto), Applicants enclose certified copy of Danish application nos. PA 1998 00909, filed July 8, 1998 and PA 1998 01500, filed November 17, 1998, priority of which is claimed under 35 U.S.C. 119.

Please charge any required fee, with this paper and credit any overpayments to Novo Nordisk Pharmaceuticals, Inc., Deposit Account No. 14-1447. Please charge any additional fees, should they be required, to Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,

Date: December 10, 2002

Marc A. Began, Reg. No. 48,829
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5800

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

NOV 26 2002

5637.200-US

STEVE T ZELSON
NOVO NORDISK OF NORTH AMERICA INC

405 LEXINGTON AVENUE SUITE 6400
NEW YORK NY 10174-6401

Serial No. : 09/348,536
Applicant : Buch-Rassmussen et al
Filing Date : 07/07/1999
Date Mailed : 11/13/2002

DOCKET (check off ✓)
ATTY:
MAB Dckt 12/2/03

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given 30 days from the mail date of this Notice within which to correct the informalities indicated below. A failure to reply will result in the application being ABANDONED. This period for reply is NOT extendable under 37 CFR 1.136 (a)

.TOP SHEETS OF FOREIGN PRIORITY DOCUMENTS ARE REQUIRED.

APPLICANT MUST SUPPLY TOP SHEETS WITHIN 30 DAYS OF THE MAIL DATE OF THIS NOTICE.

A copy of this notice MUST be returned with the reply. Please address response to "Box Issue Fee".

David Irvine
Data Query
Phone: Dial 1-800-877-8339; ask relay to dial 703-305-8418
Fax: 703-308-6642

Per Overg
Use these as certified Copys

Kongeriget Danmark

Patent application No.: PA 1998 00909

Date of filing: 08 July 1998

Applicant: Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd

This is to certify the correctness of the following information:

The attached photocopy is a true copy of the following information:

- The specification, claims and figures as filed with the application on the filing date indicated above.

Patent- og Varemærkestyrelsen
Økonomi- og Erhvervsministeriet

TAASTRUP 03 December 2002

Karin Schlichting
Head Clerk

PATENT- OG VAREMÆRKESTYRELSEN

Use as certified copy.

Kongeriget Danmark

Patent application No.: PA 1998 01500

Date of filing: 17 November 1998

Applicant: Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd

This is to certify the correctness of the following information:

The attached photocopy is a true copy of the following information:

The specification, claims and figures as filed with the application on the filing date indicated above.

Patent- og Varemærkestyrelsen
Økonomi- og Erhvervsministeriet

TAASTRUP 03 December 2002

Karin Schlichting
Head Clerk
PATENT- OG VAREMÆRKESTYRELSEN

SAN00828366

#24
DE
11/13/02

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

STEVE T ZELSON
NOVO NORDISK OF NORTH AMERICA INC

405 LEXINGTON AVENUE SUITE 6400
NEW YORK NY 10174-6401

Serial No. : 09/348,536
Applicant : Buch-Rassmussen et al
Filing Date : 07/07/1999
Date Mailed : 11/13/2002

NOTICE TO FILE CORRECTED APPLICATION PAPERS

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A copy of this notice MUST be returned with the reply. Please address response to "Box Issue Fee".

David Irvine
Data Query
Phone: Dial 1-800-877-8339; ask relay to dial 703-305-8418
Fax: 703-308-6642

B

Attorney Docket No.: 5637.200-US

PATENT

Ok to Enter

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/348,536

Group Art Unit: 3763

Filed: July 7, 1999

Examiner: Simmons, Kevin C

Confirmation No: 5366

Part of #25

For: Medication Delivery Device

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

Commissioner for Patents
Washington, DC 20231

Sir:

I hereby certify that the attached correspondence comprising:

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3. Copy of Notice to File Corrected Application Papers
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is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

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Attorney Docket No.: 5637.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/348,536 Group Art Unit:

Filed: July 7, 1999 Examiner: To be assigned

Confirmation No: 5366

For: Medication Delivery Device

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Commissioner for Patents
Washington, DC 20231

Sir:

In response to the Notice to File Corrected Application Papers dated November 13, 2002, (a copy thereof is attached hereto), Applicants enclose certified copy of Danish application nos. PA 1998 00909, filed July 8, 1998 and PA 1998 01500, filed November 17, 1998, priority of which is claimed under 35 U.S.C. 119.

Please charge any required fee, with this paper and credit any overpayments to Novo Nordisk Pharmaceuticals, Inc., Deposit Account No. 14-1447. Please charge any additional fees, should they be required, to Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

Respectfully submitted,

Date: December 10, 2002

Marc A. Began, Reg. No. 48,829
Novo Nordisk Pharmaceuticals, Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5800

Attorney Docket No.: 5637.200-US

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

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UNITED STATES PATENT AND TRADEMARK OFFICE (M5187)

COMMISSIONER FOR PATENTS
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5637.200-US

STEVE T ZELSON
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405 LEXINGTON AVENUE SUITE 6400
NEW YORK NY 10174-6401

Serial No. : 09/348,536
Applicant : Buch-Rassmussen et al
Filing Date : 07/07/1999
Date Mailed : 11/13/2002

DOCKET (check off ✓)
ATTY:
MAB DCKT 12/2/02

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Notice of Allowance Mailed

This application has been accorded an Allowance Date and is being prepared for issuance. The application, however, is incomplete for the reasons below.

Applicant is given 30 days from the mail date of this Notice within which to correct the informalities indicated below. A failure to reply will result in the application being ABANDONED. This period for reply is NOT extendable under 37 CFR 1.136 (a)

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APPLICANT MUST SUPPLY TOP SHEETS WITHIN 30 DAYS OF THE MAIL DATE OF THIS NOTICE.

A copy of this notice MUST be returned with the reply. Please address response to "Box Issue Fee".

David Irvine
Data Query
Phone: Dial 1-800-877-8339; ask relay to dial 703-305-8418
Fax: 703-308-6642

Kongeriget Danmark

Patent application No.: PA 1998 00909

Date of filing: 08 July 1998

Applicant: Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd

This is to certify the correctness of the following information:

The attached photocopy is a true copy of the following information:

- The specification, claims and figures as filed with the application on the filing date indicated above.

Patent- og Varemærkestyrelsen
Økonomi- og Erhvervsministeriet

TAASTRUP 03 December 2002

Karin Schlichting
Head Clerk

PATENT- OG VAREMÆRKESTYRELSEN

SAN00828372

08/07/98 13:01 HEIDEN & HOIBERG → 43508001 Modtaget PD NR.570 03
- 8 JULI 1998

The present invention relates to a medication delivery device having a cartridge and a dosing assembly coupled together for delivering selected doses of medication, wherein at least one of the coupling means of the cartridge is unitarily moulded with the cartridge.

Background

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the day. The required insulin dose will vary from patient to patient, and will for each patient often also vary during the day. Each patient will often establish a regimen for the insulin administration adjusted to his or her insulin need as well as lifestyle. Medication delivery pens have been developed to facilitate the self-administration of medication, such as insulin.

One prior art medication delivery pen includes a pen body assembly comprising a medication cartridge and a plunger device. A needle assembly may be connected to the pen body assembly. The medication is delivered by moving or pressing a plunger in the direction of the needle assembly thereby delivering the medication. When the medication in the cartridge is exhausted the pen body assembly is discarded. Depending on the medication needs for each individual the medication in the cartridge will last for several days. During this period the needle assembly will often have to be displaced by a new assembly or new needle due to increasing bluntness of the needle making injections painful for the patient.

More recent developments have revealed medication delivery pens, wherein the cartridge holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, discarded and replaced by a new medicine-containing cartridge assembly.

An example of this is shown in EP 0 666 571 disclosing a medication delivery pen having a reusable pen body assembly and a disposable cartridge assembly that are threadedly engageable with one another. The cartridge assembly comprises a cartridge, a cartridge housing, a cap between the distal end of the cartridge and the housing, securing the cartridge in the housing and being adapted for engagement

with a needle assembly. Furthermore, the cartridge comprises a plunger within the cartridge. The reusable pen body assembly is coupled through a threaded coupling to the cartridge housing. Thus, the total number of parts comprising the prior art cartridge assembly is high.

It is an object of the present invention to provide a medication delivery device wherein the amount of parts of the cartridge is minimized.

Summary of the invention

Accordingly, the present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly,

said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, the cartridge further comprising a stopper adapted to receive plunger means, and

said dosing assembly comprising plunger means has coupling means for engaging the cartridge assembly, and said plunger means is adapted to engage the stopper of the cartridge when the dosing assembly is coupled to the cartridge.

The above-described medication delivery device has fewer parts that the prior art devices because at least one coupling means is moulded unitarily with the cartridge. Thereby the costs involved in the production and assembling of the device are reduced, and the device is more economical, which is an important feature for a disposable device.

The medical delivering device may either be manufactured as a disposable device which is sold pre-filled with the insulin or it may appear as a durable medical delivering device so designed that it can receive disposable cartridges with insulin.

In a preferred embodiment the dosing assembly is reusable and the cartridge assembly is disposable, and accordingly, a second aspect of the present invention is a medication delivery device wherein the dosing assembly is releasably coupled to the cartridge assembly.

The medication delivery device is preferably constructed as to secure that the plunger means abuts on the stopper during use of the device, such as attaching and releasing the needle assembly. It is understood that the plunger means must disengage the stopper when the cartridge assembly is deliberately released from a reusable dosing assembly because the medication in the cartridge has been exhausted and the cartridge assembly is to be discarded. In this situation the plunger means is to be retracted to the dosing assembly before assembling the device with a new cartridge assembly.

Securing the abutment of the plunger means on the stopper during use of the medication delivery device, in particular when the needle assembly is coupled to and/or decoupled from the cartridge assembly, may be carried out by a variety of means. In a preferred embodiment the abutment is secured by preventing the cartridge assembly from being inadvertently released from the dosing assembly.

In particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dosing assembly. Thus, in that respect examples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks. Another preferred embodiment includes a safety on the coupling between the dosing assembly and the cartridge assembly, such as hinge on the coupling or a threaded coupling releasable only after exerting an axial pressure on the coupling.

A second aspect of the present invention is a cartridge assembly for use in a medication delivery device, said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, said cartridge further comprising a stopper.

The cartridge assembly may further comprise a cartridge housing for protecting the cartridge in use. Furthermore, when the cartridge is moulded unitarily with one coupling means the cartridge housing may comprise the other coupling means. Accordingly, in one embodiment of the invention the housing of the cartridge assembly comprises coupling means for coupling the cartridge assembly to the dosing assembly, preferably the coupling means is moulded unitarily with the housing. The cartridge is arranged within the cartridge housing. The cartridge housing may be non-releasably attached to the cartridge, once the cartridge is arranged in the housing, whereby the housing is disposed with the cartridge. In another embodiment the housing is reusable and the cartridge is arranged releasably in the housing.

In a preferred embodiment all the coupling means of the cartridge assembly are unitarily moulded with the cartridge. Thereby, it is possible to construct the cartridge assembly without the housing providing a cartridge assembly with even fewer parts.

The coupling means of the cartridge assembly may be for any suitable coupling, preferably a releasable coupling. Examples of the coupling are snap locks, such as snap locks with guidewire and sideways snap locks, snap locks released through threads, bajonet locks, luer locks, hinged locks, threaded locks and any suitable combinations thereof.

The coupling means unitarily moulded with the cartridge are preferably external coupling means, such as an external threaded coupling.

The cartridge may be moulded from any material suitable for medical containers. The cartridge is preferably moulded from a plastic material, e.g. by injection moulding. A suitable choice of material allows the cartridge to be at least partly transpar-

ent, whereby the user can see whether liquid is left in the cartridge. In a preferred embodiment the cartridge is totally transparent giving the user a greater possibility of inspecting the content of the cartridge.

By using a plastic material as compared to the usual glass material a great advantage is achieved in the production lines. Normally a significant quantity of the produced glass cartridges will be spoiled in the lines due to breakage, however the loss is greatly reduced by the use of plastic cartridges. Furthermore, the risk of small loose glass particles in the cartridges have been eliminated.

The cartridge may be of any suitable form, such as a cylinder. The cylinder may be constructed with various combinations of circular or non-circular inner and outer cross-section. In another embodiment the cartridge may be box-shaped having essentially rectangular or triangular cross-section.

The stopper is in sliding fluid tight engagement in the cartridge. The stopper is preferably made of plastic and/or rubber material.

The flexibility of the cartridge wall is not critical, however if the cartridge is too flexible the function of the stopper may be impaired. Mostly, the cartridge is made of a material only slightly flexible to non-flexible.

In order to enforce and strengthen the cartridge wall the cartridge may be integrally moulded with reinforcements. Thereby, the necessity of a protective housing may be obviated. Furthermore, a scale may be integrally moulded with the cartridge wall providing the user with a measure for the medication used and left.

In a most preferred embodiment the cartridge assembly is comprised only of a cartridge being sealed in one end with a sealing, being unitarily moulded with all couplings means and comprising a stopper.

In a cylindrical cartridge the two couplings of the cartridge assembly are generally opposing each other. However, the coupling for engaging with the dosing assembly being separate from coupling for engaging the needle assembly may be arranged in any angle with respect to the latter coupling.

Another aspect of the present invention is a cartridge being at least partly filled with liquid medication, such as insulin.

Drawings

Fig. 1 is an exploded perspective view of the medication delivery device.

Fig. 2 is a cross-sectional view showing part of the medication delivery device, 2a immediately after assembling before the first injection, and 2b after some time of use.

Fig. 3 is a cross-sectional view showing the cartridge before assembling of the medication delivery device.

Detailed description of the invention

A medication delivery device in accordance with the present invention is identified generally by the numeral 20 in Fig. 1 and 2. Medication delivery device 20 includes a dosing assembly 6, and cartridge assembly 1, a needle assembly 16 and a cap 14.

The dosing assembly 6 is illustrated in Fig. 1 and 2. It is understood, however, that the dosing assembly 6 according to the invention may be any suitable dosing unit including plunger means, and accordingly, that variations from the depicted embodiment may be provided, and are considered to be within the scope of this invention. In the depicted embodiment the dosing assembly 6 includes a cylindrical housing surrounding the plunger means 17 of the dosing unit and having opposed proximal and distal ends.

In one aspect of the invention the plunger means comprises a rod element 7 which is adapted to engage the stopper 4 of the cartridge assembly 1. The rod element 7 advances axially into the cartridge 5 during injections. The dosing assembly may have any suitable driving means for advancing the rod element 7.

The dosing unit 6 preferably also comprises scale means 10 indicating the dosing quantity selected by activating the dose setting means 9 for defining specified selected doses of medication to be delivered. The selected dose may be delivered by actuating the actuator button 18. The actuator button is part of the driving means of the dosing assembly exerting its force on the rod element 7.

The dosing assembly further comprises coupling means 8 adapted for engagement with the cartridge assembly. The coupling means 8 may be internal or external couplings. In a preferred embodiment the coupling 8 is an internal coupling.

The cartridge assembly 1 is illustrated in Fig. 1 and 2, and in greater detail in Fig. 3. In Fig. 1 cartridge assembly 1 includes a moulded cartridge 5 extending from proximal end 21 to distal end 22.

At the distal end 22 of the cartridge assembly 1 is provided coupling means 2 for releasably mounting a needle assembly 11. At the proximal end 21 of the cartridge assembly 1 is provided coupling means 3 for mounting a dosing assembly 6. The coupling means are as described above.

Cartridge 5 also comprises a stopper 4 in sliding fluid tight engagement within said cartridge 5. The stopper 4 is adapted to receive the plunger means, such as a rod element 7 of the dosing assembly 6. The rod element 7 is adapted to exert an axial movement of the stopper 4 towards the sealed end 22 of the cartridge 5.

The cartridge assembly 1 may further comprise a housing for protecting some or all of the cartridge 5. When the cartridge assembly 1 includes a housing, one of the couplings 2, 3 of the cartridge may be moulded unitarily with the housing.

Instead of the protective housing the cartridge 5 may have integrally moulded reinforcements of the cartridge wall.

The depicted cartridge 5 is cylindrical having couplings 2, 3 at opposed ends. However, the cartridge may obtain any suitable form and the cross-section may be circular or non-circular, such as substantially triangular or oval.

The device according to the invention may include a protective cap 14 that is removably mounted over the cartridge assembly 1 and/or the needle 11 and which is removed before injection of the medication in the cartridge 5. The cap further ensures that the content of the cartridge is protected against sunlight.

Referring to Fig. 3 the coupling means of the cartridge are shown in greater detail. The coupling means 3 is an external thread, whereas the coupling means 2 is a recess for a snap lock of the needle assembly. Both coupling means are moulded unitarily with the cartridge.

The various parts of the medication delivery device are advantageously made of plastics, e.g. by injection moulding.

The medication delivery device 20 may further comprise any appropriate needle assembly 11, such as a double ended needle 13 having opposed proximal and distal points and a lumen extending axially therebetween.

A mounting hub 12 is engaged on the needle 13 and is removably connected to the coupling means 2 at the needle end of the cartridge assembly. The relative location of the mounting hub 12 ensures that the proximal point of the needle 13 will pierce the sealing when the mounting hub 12 is engaged with the coupling means 2 on the cartridge assembly 1.

The needle assembly 11 may further comprise a removable shield or cap 15 for protecting against accidental needle sticks.

The device according to the invention is suitable for delivering pre-set dosages of insulin, it is however understood that the device is suitable for the injection of pre-set dosages of other liquids.

In use the user will set the dose by means of the dose setting means 9. Before activating the actuator button 18 the cap 14 must be removed from the cartridge assembly 1 whereby the device 20 is prepared for an injection. The injection is effected by activating the actuator button 18, which again will affect the stopper 4 to be moved towards the sealed end 22 of the cartridge 5, thereby delivering the desi-

red pre-set dosage. A subsequent dosage of medication will be set in exactly the same manner as described above. However, for such a subsequent dosage, the rod element 7 and the stopper 4 will be in a partly advanced position as starting point. Dose setting and injections can be carried out until all of the medication has been used.

Claims:

1. A medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly,

said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, the cartridge further comprising a stopper adapted to receive plunger means, and

said dosing assembly comprising plunger means having coupling means for engaging the cartridge, and said plunger means is adapted to engage the stopper of the cartridge when the dosing assembly is coupled to the cartridge.

2. A medication delivery device according to claim 1, wherein all the coupling means of the cartridge assembly are unitarily moulded with the cartridge.

3. A medication delivery device according to claim 1 or 2, wherein at least one coupling means of the cartridge is an external coupling.

4. A medication delivery device according to any of the preceding claims, wherein at least one coupling means of the cartridge is a threaded coupling.

5. A medication delivery device according to any of the preceding claims, wherein the cartridge is moulded of a plastic material.

6. A medication delivery device according to any of the preceding claims, wherein the cartridge is at least partly transparent.

7. A medication delivery device according to any of the preceding claims, wherein reinforcements of the cartridge wall are integrally moulded with the cartridge.

8. A medication delivery device according to any of the preceding claims, wherein the cartridge further comprises a cartridge housing.

9. A medication delivery device according to any of the preceding claims, wherein the cartridge further comprise a scale.

10. A medication delivery device according to any of the preceding claims, wherein the cross-section of the cartridge is non-circular.

11. A medication delivery device according to any of the preceding claims, wherein the coupling means of the cartridge are opposed each other.

12. A cartridge assembly for use in a medication delivery device, said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, said cartridge further comprising a stopper.

13. A cartridge assembly according to claim 12, wherein all the coupling means of the cartridge are unitarily moulded with the cartridge.

14. A cartridge assembly according to claim 12 or 13, wherein at least one coupling means of the cartridge is an external coupling.

15. A cartridge assembly according to any of the claims 12-14, wherein at least one coupling means of the cartridge is a threaded coupling.

16. A cartridge assembly according to any of the claims 12-15, wherein the cartridge is moulded of a plastic material.

17. A cartridge assembly according to any of the preceding 12-16, wherein the cartridge is at least partly transparent.

18. A cartridge assembly according to any of the claims 12-17, wherein reinforcements of the cartridge wall are integrally moulded with the cartridge.

19. A cartridge assembly according to any of the claims 12-18, wherein the cartridge further comprises a cartridge housing.

20. A cartridge assembly according to any of the claims 12-19, wherein the cartridge further comprise a scale.

21. A cartridge assembly according to any of the claims 12-20, wherein the cross-section of the cartridge is non-circular.

22. A cartridge assembly according to any of the claims 12-21, wherein the coupling means of the cartridge are opposed each other.

23. A cartridge assembly according to any of the claims 12-22, which is filled with medicine.

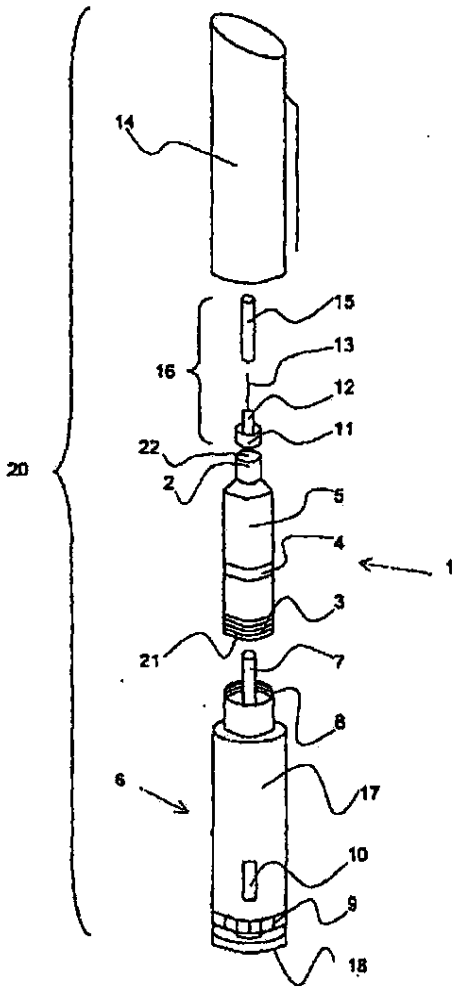

Fig. 1

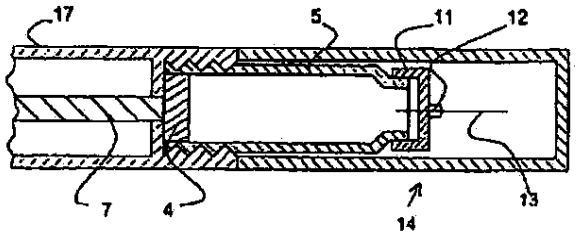

Fig. 2 a

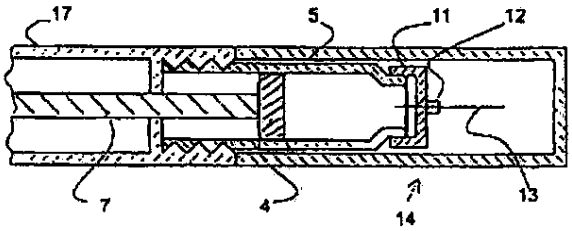

Fig. 2 b

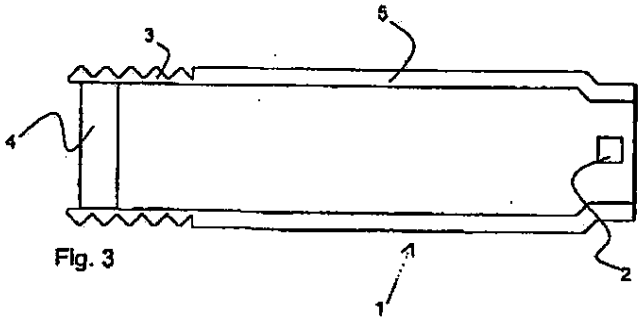

Fig. 3

Kongeriget Danmark

Patent application No.: PA 1998 01500

Date of filing: 17 November 1998

Applicant: Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd

This is to certify the correctness of the following information:

The attached photocopy is a true copy of the following information:

- The specification, claims and figures as filed with the application on the filing date indicated above.

Patent- og Varemærkestyrelsen
Økonomi- og Erhvervsministeriet

TAASTRUP 03 December 2002

Karin Schlichting
Head Clerk
PATENT- OG VAREMÆRKESTYRELSEN

SAN00828387

The present invention relates to a medication delivery device having a cartridge and a dosing assembly coupled together for delivering selected doses of medication, wherein at least one of the coupling means of the cartridge is unitarily moulded with the cartridge.

Background

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the day. The required insulin dose will vary from patient to patient, and will for each patient often also vary during the day. Each patient will often establish a regimen for the insulin administration adjusted to his or her insulin need as well as lifestyle. Medication delivery pens have been developed to facilitate the self-administration of medication, such as insulin.

One prior art medication delivery pen includes a pen body assembly comprising a medication cartridge and a plunger device. A needle assembly may be connected to the pen body assembly. The medication is delivered by moving or pressing a plunger in the direction of the needle assembly thereby delivering the medication. When the medication in the cartridge is exhausted the pen body assembly is discarded. Depending on the medication needs for each individual the medication in the cartridge will last for several days. During this period the needle assembly will often have to be displaced by a new assembly or new needle due to increasing bluntness of the needle making injections painful for the patient.

More recent developments have revealed medication delivery pens, wherein the cartridge holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, discarded and replaced by a new medicine-containing cartridge assembly.

An example of this is shown in EP 0 688 571 disclosing a medication delivery pen having a reusable pen body assembly and a disposable cartridge assembly that are threadedly engageable with one another. The cartridge assembly comprises a cartridge, a cartridge housing, a cap between the distal end of the cartridge and the housing, securing the cartridge in the housing and being adapted for engagement

with a needle assembly. Furthermore, the cartridge comprises a plunger within the cartridge. The reusable pen body assembly is coupled through a threaded coupling to the cartridge housing. Thus, the total number of parts comprising the prior art cartridge assembly is high.

It is an object of the present invention to provide a medicalton delivery device wherein the amount of parts of the cartridge is minimised.

Summary of the Invention

Accordingly, the present invention relates to a medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly,

said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, the cartridge further comprising a stopper adapted to receive plunger means, and

said dosing assembly comprising plunger means has coupling means for engaging the cartridge assembly, and said plunger means is adapted to engage the stopper of the cartridge when the dosing assembly is coupled to the cartridge.

The above-described medication delivery device has fewer parts that the prior art devices becasuse at least one coupling means is moulded unitarily with the cartridge. Thereby the costs involved in the production and assembling of the device are reduced, and the device is more economical, which is an important feature for a disposable device.

The medical delivering device may either be manufactured as a disposable device which is sold pre-filled with the insulin or it may appear as a durable medical delivering device so designed that it can receive disposable cartridges with insulin.

In a preferred embodiment the dosing assembly is reusable and the cartridge assembly is disposable, and accordingly, a second aspect of the present invention is a medication delivery device wherein the dosing assembly is releasably coupled to the cartridge assembly.

The medication delivery device is preferably constructed as to secure that the plunger means abuts on the stopper during use of the device, such as attaching and releasing the needle assembly. It is understood that the plunger means must disengage the stopper when the cartridge assembly is deliberately released from a reusable dosing assembly because the medication in the cartridge has been exhausted and the cartridge assembly is to be discarded. In this situation the plunger means is to be retracted to the dosing assembly before assembling the device with a new cartridge assembly.

Securing the abutment of the plunger means on the stopper during use of the medication delivery device, in particular when the needle assembly is coupled to and/or decoupled from the cartridge assembly, may be carried out by a variety of means. In a preferred embodiment the abutment is secured by preventing the cartridge assembly from being inadvertently released from the dosing assembly.

In particular, when the cartridge assembly is released from the dosing assembly through a movement including an axial movement, such as through a threaded coupling, it is preferred that the means for releasably coupling the needle assembly and the cartridge assembly together are such that the coupling and/or decoupling of the needle assembly cannot cause an axial movement of the cartridge assembly with respect to the dosing assembly. Thus, in that respect examples of the preferred couplings between the needle assembly and the cartridge assembly include releasable snap locks. Another preferred embodiment includes a safety on the coupling between the dosing assembly and the cartridge assembly, such as hinge on the coupling or a threaded coupling releasable only after exerting an axial pressure on the coupling.

A second aspect of the present invention is a cartridge assembly for use in a medication delivery device, said cartridge assembly having one end sealed with a piercable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, said cartridge further comprising a stopper.

The cartridge assembly may further comprise a cartridge housing for protecting the cartridge in use. Furthermore, when the cartridge is moulded unitarily with one coupling means the cartridge housing may comprise the other coupling means. Accordingly, in one embodiment of the invention the housing of the cartridge assembly comprises coupling means for coupling the cartridge assembly to the dosing assembly, preferably the coupling means is moulded unitarily with the housing. The cartridge is arranged within the cartridge housing. The cartridge housing may be non-releasably attached to the cartridge, once the cartridge is arranged in the housing, whereby the housing is disposed with the cartridge. In another embodiment the housing is reusable and the cartridge is arranged releasably in the housing.

In a preferred embodiment all the coupling means of the cartridge assembly are unitarily moulded with the cartridge. Thereby, it is possible to construct the cartridge assembly without the housing providing a cartridge assembly with even fewer parts.

The coupling means of the cartridge assembly may be for any suitable coupling, preferably a releasable coupling. Examples of the coupling are snap locks, such as snap locks with guidewire and sideways snap locks, snap locks released through threads, bajonet locks, luer locks, hinged locks, threaded locks and any suitable combinations thereof.

The coupling means unitarily moulded with the cartridge are preferably external coupling means, such as an external threaded coupling.

The cartridge may be moulded from any material suitable for medical containers. The cartridge is preferably moulded from a plastic material, e.g. by injection moulding. A suitable choice of material allows the cartridge to be at least partly transpar-

ent, whereby the user can see whether liquid is left in the cartridge. In a preferred embodiment the cartridge is totally transparent giving the user a greater possibility of inspecting the content of the cartridge.

By using a plastic material as compared to the usual glass material a great advantage is achieved in the production lines. Normally a significant quantity of the produced glass cartridges will be spoiled in the lines due to breakage, however the loss is greatly reduced by the use of plastic cartridges. Furthermore, the risk of small loose glass particles in the cartridges have been eliminated.

The cartridge may be of any suitable form, such as a cylinder. The cylinder may be constructed with various combinations of circular or non-circular inner and outer cross-section. In another embodiment the cartridge may be box-shaped having essentially rectangular or triangular cross-section.

The stopper is in sliding fluid tight engagement in the cartridge. The stopper is preferably made of plastic and/or rubber material.

The flexibility of the cartridge wall is not critical, however if the cartridge is too flexible the function of the stopper may be impaired. Mostly, the cartridge is made of a material only slightly flexible to non-flexible.

In order to enforce and strengthen the cartridge wall the cartridge may be integrally moulded with reinforcements. Thereby, the necessity of a protective housing may be obviated. Furthermore, a scale may be integrally moulded with the cartridge wall providing the user with a measure for the medication used and left.

In a most preferred embodiment the cartridge assembly is comprised only of a cartridge being sealed in one end with a sealing, being unitarily moulded with all couplings means and comprising a stopper.

In a cylindrical cartridge the two couplings of the cartridge assembly are generally opposing each other. However, the coupling for engaging with the dosing assembly being separate from coupling for engaging the needle assembly may be arranged in any angle with respect to the latter coupling.

Another aspect of the present invention is a cartridge being at least partly filled with liquid medication, such as insulin.

In another embodiment the invention relates to a medication delivery device for transferring medication from the cartridge into a syringe with a needle. In this embodiment the coupling means for engaging the needle assembly may be replaced by coupling means for engaging the syringe, or coupling means for both may be provided. The coupling means may be a syringe holder, for example a cylinder coupled to the cartridge comprising a central bore for receiving the syringe. The syringe is coupled to the cartridge having the needle piercing the sealing. By activation of the dosing means the metered amount of medication is driven into the syringe. The syringe is then ready for injection after being removed from the cartridge.

Drawings

Fig. 1 is an exploded perspective view of the medication delivery device.

Fig. 2 is a cross-sectional view showing part of the medication delivery device, 2a immediately after assembling before the first injection, and 2b after some time of use.

Fig. 3 is a cross-sectional view showing the cartridge before assembling of the medication delivery device.

Detailed description of the invention

A medication delivery device in accordance with the present invention is identified generally by the numeral 20 in Fig. 1 and 2. Medication delivery device 20 includes a dosing assembly 6, and cartridge assembly 1, a needle assembly 18 and a cap 14.

The dosing assembly 6 is illustrated in Fig. 1 and 2. It is understood, however, that the dosing assembly 6 according to the invention may be any suitable dosing unit including plunger means, and accordingly, that variations from the depicted embodiment may be provided, and are considered to be within the scope of this inven-

tion. In the depicted embodiment the dosing assembly 6 includes a cylindrical housing surrounding the plunger means 17 of the dosing unit and having opposed proximal and distal ends.

In one aspect of the invention the plunger means comprises a rod element 7 which is adapted to engage the stopper 4 of the cartridge assembly 1. The rod element 7 advances axially into the cartridge 5 during injections. The dosing assembly may have any suitable driving means for advancing the rod element 7.

The dosing unit 6 preferably also comprises scale means 10 indicating the dosing quantity selected by activating the dose setting means 9 for defining specified selected doses of medication to be delivered. The selected dose may be delivered by actuating the actuator button 18. The actuator button is part of the driving means of the dosing assembly exerting its force on the rod element 7.

The dosing assembly further comprises coupling means 8 adapted for engagement with the cartridge assembly. The coupling means 8 may be internal or external couplings. In a preferred embodiment the coupling 8 is an internal coupling.

The cartridge assembly 1 is illustrated in Fig. 1 and 2, and in greater detail in Fig. 3. In Fig. 1 cartridge assembly 1 includes a moulded cartridge 5 extending from proximal end 21 to distal end 22.

At the distal end 22 of the cartridge assembly 1 is provided coupling means 2 for releasably mounting a needle assembly 11. At the proximal end 21 of the cartridge assembly 1 is provided coupling means 3 for mounting a dosing assembly 6. The coupling means are as described above.

Cartridge 5 also comprises a stopper 4 in sliding fluid tight engagement within said cartridge 5. The stopper 4 is adapted to receive the plunger means, such as a rod element 7 of the dosing assembly 6. The rod element 7 is adapted to exert an axial movement of the stopper 4 towards the sealed end 22 of the cartridge 5.

The cartridge assembly 1 may further comprise a housing for protecting some or all of the cartridge 5. When the cartridge assembly 1 includes a housing, one of the couplings 2, 3 of the cartridge may be moulded unitarily with the housing.

Instead of the protective housing the cartridge 5 may have integrally moulded reinforcements of the cartridge wall.

The depicted cartridge 5 is cylindrical having couplings 2, 3 at opposed ends. However, the cartridge may obtain any suitable form and the cross-section may be circular or non-circular, such as substantially triangular or oval.

The device according to the invention may include a protective cap 14 that is removably mounted over the cartridge assembly 1 and/or the needle 11 and which is removed before injection of the medication in the cartridge 5. The cap further ensures that the content of the cartridge is protected against sunlight.

Referring to Fig. 3 the coupling means of the cartridge are shown in greater detail. The coupling means 3 is an external thread, whereas the coupling means 2 is a recess for a snap lock of the needle assembly. Both coupling means are moulded unitarily with the cartridge.

The various parts of the medication delivery device are advantageously made of plastics, e.g. by injection moulding.

The medication delivery device 20 may further comprise any appropriate needle assembly 11, such as a double ended needle 13 having opposed proximal and distal points and a lumen extending axially therebetween.

A mounting hub 12 is engaged on the needle 13 and is removably connected to the coupling means 2 at the needle end of the cartridge assembly. The relative location of the mounting hub 12 ensures that the proximal point of the needle 13 will pierce the sealing when the mounting hub 12 is engaged with the coupling means 2 on the cartridge assembly 1.

The needle assembly 11 may further comprise a removable shield or cap 15 for protecting against accidental needle sticks.

The device according to the invention is suitable for delivering pre-set dosages of insulin, it is however understood that the device is suitable for the injection of pre-set dosages of other liquids.

In use the user will set the dose by means of the dose setting means 9. Before activating the actuator button 18 the cap 14 must be removed from the cartridge assembly 1 whereby the device 20 is prepared for an injection. The injection is effected by activating the actuator button 18, which again will effect the stopper 4 to be moved towards the sealed end 22 of the cartridge 5, thereby delivering the desired pre-set dosage. A subsequent dosage of medication will be set in exactly the same manner as described above. However, for such a subsequent dosage, the rod element 7 and the stopper 4 will be in a partly advanced position as starting point. Dose setting and injections can be carried out until all of the medication has been used.

Claims:

1. A medication delivery device comprising a cartridge assembly, a dosing assembly and optionally a needle assembly,

said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, the cartridge further comprising a stopper adapted to receive plunger means, and

said dosing assembly comprising plunger means having coupling means for engaging the cartridge, and said plunger means is adapted to engage the stopper of the cartridge when the dosing assembly is coupled to the cartridge.

2. A medication delivery device according to claim 1, wherein all the coupling means of the cartridge assembly are unitarily moulded with the cartridge.

3. A medication delivery device according to claim 1 or 2, wherein at least one coupling means of the cartridge is an external coupling.

4. A medication delivery device according to any of the preceding claims, wherein at least one coupling means of the cartridge is a threaded coupling.

5. A medication delivery device according to any of the preceding claims, wherein the cartridge is moulded of a plastic material.

6. A medication delivery device according to any of the preceding claims, wherein the cartridge is at least partly transparent.

7. A medication delivery device according to any of the preceding claims, wherein reinforcements of the cartridge wall are integrally moulded with the cartridge.

8. A medication delivery device according to any of the preceding claims, wherein the cartridge further comprises a cartridge housing.

9. A medication delivery device according to any of the preceding claims, wherein the cartridge further comprise a scale.

10. A medication delivery device according to any of the preceding claims, wherein the cross-section of the cartridge is non-circular.

11. A medication delivery device according to any of the preceding claims, wherein the coupling means of the cartridge are opposed each other.

12. A cartridge assembly for use in a medication delivery device, said cartridge assembly having one end sealed with a pierceable sealing, said end of the cartridge assembly comprising coupling means for engaging a needle assembly, and another end comprising coupling means for engaging the dosing assembly, said cartridge assembly further comprising a cartridge wherein at least one of the coupling means of said cartridge assembly is unitarily moulded with the cartridge, said cartridge further comprising a stopper.

13. A cartridge assembly according to claim 12, wherein all the coupling means of the cartridge are unitarily moulded with the cartridge.

14. A cartridge assembly according to claim 12 or 13, wherein at least one coupling means of the cartridge is an external coupling.

15. A cartridge assembly according to any of the claims 12-14, wherein at least one coupling means of the cartridge is a threaded coupling.

16. A cartridge assembly according to any of the claims 12-15, wherein the cartridge is moulded of a plastic material.

17. A cartridge assembly according to any of the preceding 12-16, wherein the cartridge is at least partly transparent.

18. A cartridge assembly according to any of the claims 12-17, wherein reinforcements of the cartridge wall are integrally moulded with the cartridge.

19. A cartridge assembly according to any of the claims 12-18, wherein the cartridge further comprises a cartridge housing.

20. A cartridge assembly according to any of the claims 12-19, wherein the cartridge further comprise a scale.

21. A cartridge assembly according to any of the claims 12-20, wherein the cross-section of the cartridge is non-circular.

22. A cartridge assembly according to any of the claims 12-21, wherein the coupling means of the cartridge are opposed each other.

23. A cartridge assembly according to any of the claims 12-22, which is filled with medicine.

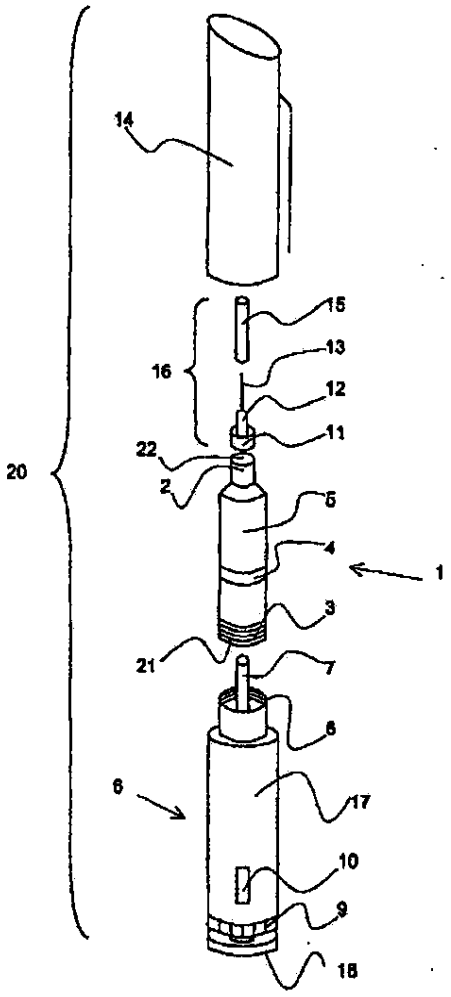

Fig. 1

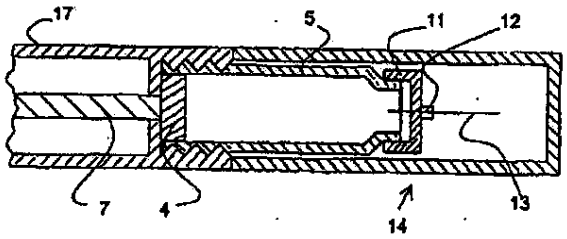

Fig. 2 a

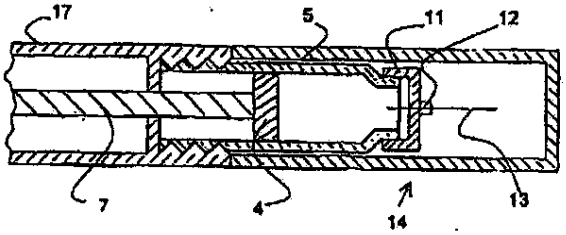

Fig. 2 b

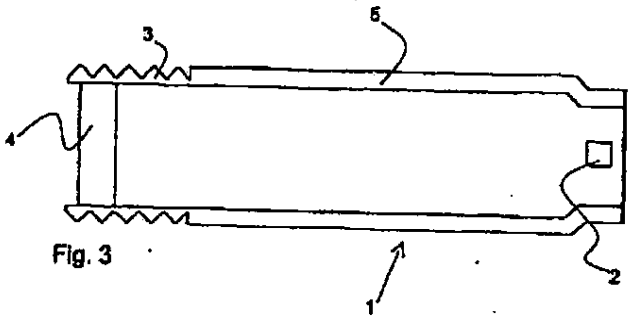

Fig. 3

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26137 7590 09/20/2002

~~PATENT DEPARTMENT~~ Marc A. Began, Esq.
~~SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP~~
~~FOUR TIMES SQUARE~~ Novo Nordisk Pharmaceuticals, Inc.
~~NEW YORK, NY 10036~~
100 College Road West
Princeton, NJ 08540

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Raghida Haji (Typed or printed name)
RHaji (Signature)
December 12, 2002 (Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/348,536	07/01/1999	THOMAS BUCH-RASMUSSEN	5637.200-US	5366

TITLE OF INVENTION: MEDICATION DELIVERY DEVICE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1280	$0	$1280	12/20/2002

EXAMINER	ART UNIT	CLASS-SUBCLASS
SIMMONS, KEVIN C	3763	604-232000

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1 Marc A. Began, Esq.
2 Richard W. Bork, Esq.
3 Reza Green, Esq.

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(B) RESIDENCE: (CITY and STATE OR COUNTRY): Bagsvaerd Denmark

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37 Klim B

Attorney Docket No.: 5637.200-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Buch-Rasmussen et al.

Serial No.: 09/348,536 Group Art Unit: 3763

Filed: July 7, 1999 Examiner: Simmons

Confirmation No: 5366

For: Medication Delivery Device

CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)

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Washington, DC 20231

Sir:

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2. 1 Sheet of Formal Drawings

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Rashida Haji
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Attorney Docket No.: 5637.200-US

PATENT

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Filed: July 7, 1999

Examiner: Simmons

Confirmation No: 5366

For: Medication Delivery Device

SUBMISSION OF FORMAL DRAWINGS

Commissioner for Patents
Washington, DC 20231

Sir:

Applicants submit herewith 1 sheet of formal drawings, containing Figures 2A, 2B and 3 for the above-captioned application. The formal drawings are being filed in response to the request contained in the Attachment to the Notice of Allowance and Issue Fee Due, mailed September 20, 2002, and should be substituted for the corresponding sheets of informal drawings of the originally filed application.

Respectfully submitted,

Date: December 12, 2002

Marc A. Began, Reg. No. 48,829
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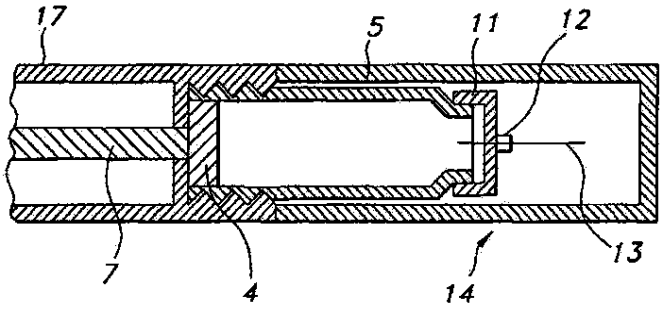

FIG. 2A

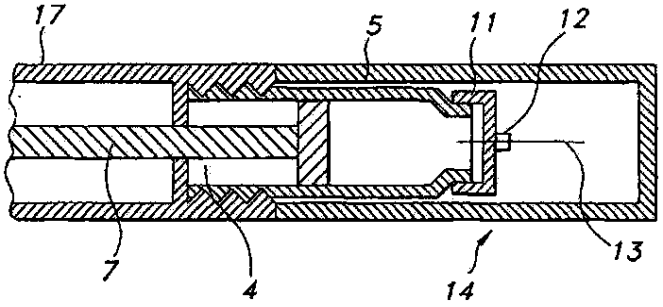

FIG. 2B

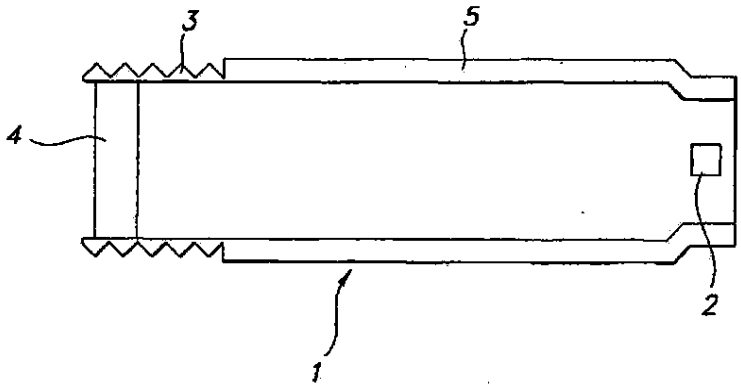

FIG. 3